Scottsdale Police Department Crime Laboratory

Calibrators and Control Certificates for Samples Run

02/10/2025 -

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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-20

Ethyl alcohol

Catalog Number:	E-056
Solution Lot:	FN03122113
Expiration:	March 2026
Diluent:	Water
Volume per Ampule:	1.2 mL
Storage:	Refrigerate (Do Not Freeze)
Intended Use:	For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- For quantitative applications, the minimum sample size for intended use is 100 µL.

Component	Solution Purity	Certified Concentration
Ethanol	> 99.9%	20.00 ± 0.08 mg/dL

- Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.194% and the relative expanded uncertainty is 0.39% at the 95% confidence interval (k=2).
- The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.
- Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.
- Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred.

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration date. Warranty applies to ampoules stored unopened and stored under the recommended storage conditions. Warranty and expiry do not extend to solutions into which this product has been incorporated. Establishment of shelf life of all such products is the responsibility of the user. This material is a product of Canada.

ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

July 27, 2021
Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock,
TX 78665, USA, Tel: 800-848-7837 / 512-238-9974; www.cerilliant.com
Sigma-Aldrich Production GmbH is a subsidiary of Merck KGaA, Darmstadt, Germany.

Traceability to SI through NIST:

- This standard has been prepared and certified under the ISO 17034 and ISO/IEC 17025 standards and meets the requirements of a Certified Reference Material as defined by ISO.
- This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

Standard Solution	Lot Number	Comparison to NIST Lot SRM 2891 mg/dL	Homogeneity % RSD
New Lot	FN03122113	20.06	0.6
Previous Lot	FN10051909	20.08	1.6
Acceptance Criteria		**± 2%**	**≤ 2**

- Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.
- The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.
- Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.
- The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.
- All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters.

Analyte Certification - Mass Balance Purity Factor

The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

Material Characterization Summary		
Analytical Test	**Method**	**Results**
Chromatographic Purity by GC/FID Analysis	SP10-0101	99.9%
Residual Water Analysis by Karl Fischer Coulometry	AM1346 [1]	0.11%
Identity by GC/MS	SP10-0105	Consistent with Structure
Mass Balance Purity Factor		99.81%

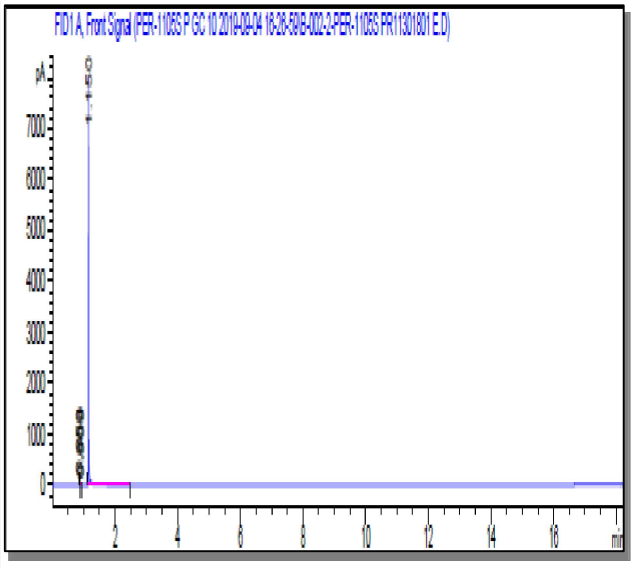
[1] Validated analytical method

- The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.

Spectral and Physical Data

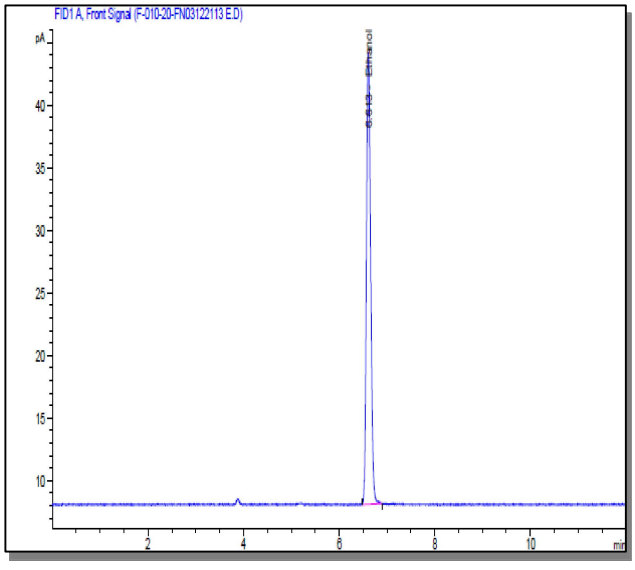
Neat Material

Analysis Method: GC/FID
Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness
Temp Program: 35°C hold 5 min to 260°C at 20°C/min hold 2 min
Injector Temp: Cool-on-Column
Detector Temp: 325°C



Standard Solution

Analysis Method: GC/FID Headspace
Column: DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness
Temp Program: 40°C hold 12 min
Injector Temp: 200°C
Detector Temp: 250°C



COA Revision History

Revision No.	Date	Reason for Revision
00	July 27, 2021	Initial version.

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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-100

Ethyl alcohol

Catalog Number:	E-031
Solution Lot:	FN03072301
Expiration:	March 2028
Diluent:	Water
Volume per Ampule:	1.2 mL
Storage:	Refrigerate (Do Not Freeze)
Intended Use:	For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- For quantitative applications, the minimum sample size for intended use is 100 µL.

Component	Solution Purity	Certified Concentration
Ethanol	> 99.9%	100.0 ± 0.4 mg/dL

- Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.194% and the relative expanded uncertainty is 0.39% at the 95% confidence interval (k=2).
- The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.
- Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.
- Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred.

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ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darren Ellsworth, Quality Assurance Manager

May 10, 2023

Date

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- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

Standard Solution	Lot Number	Comparison to NIST Lot SRM 2894 mg/dL	Homogeneity % RSD
New Lot	FN03072301	98.4	0.5
Previous Lot	FN11172002	99.0	1.0
Acceptance Criteria		**± 2%**	**≤ 2 %**

- Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.
- The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.
- Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.
- The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.
- All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters.

Analyte Certification - Mass Balance Purity Factor

The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

Material Characterization Summary		
Analytical Test	**Method**	**Results**
Chromatographic Purity by GC/FID Analysis	20384346	> 99.9%
Identity by GC/MS Analysis	20384214	Consistant with Structure
Residual Water Analysis by Karl Fischer Coulometry	20398075 [1]	0.16%
Mass Balance Purity Factor		99.84%

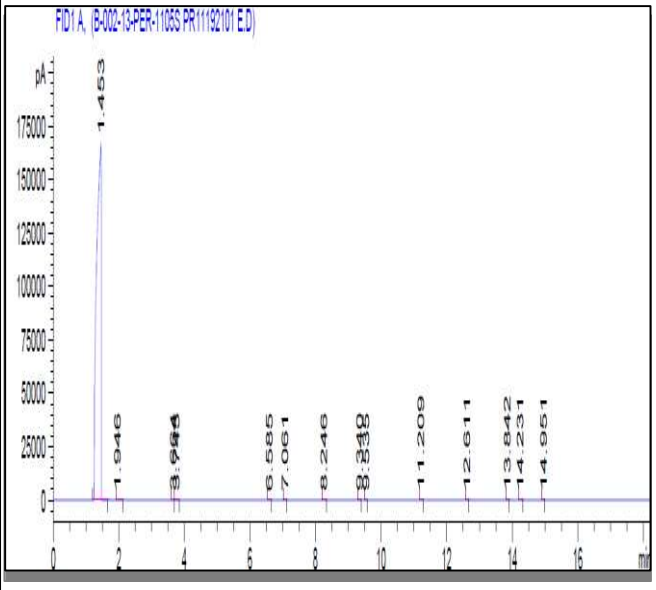
[1] Validated analytical method

- The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.

Spectral and Physical Data

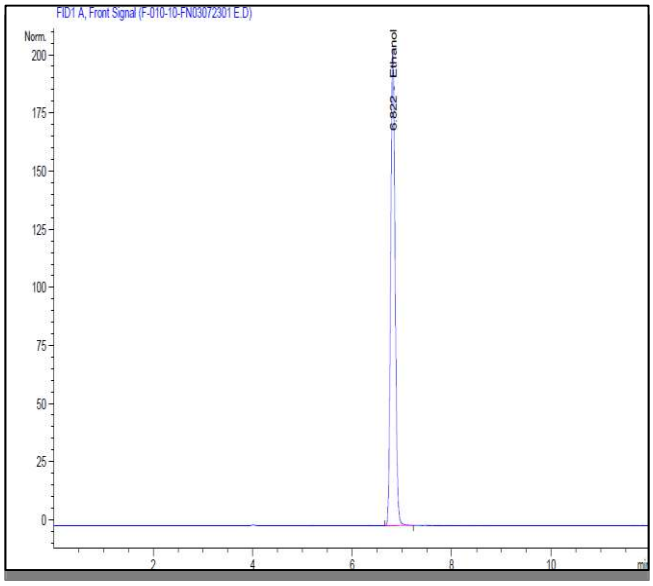
Neat Material

Analysis Method: GC/FID
Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness
Temp Program: 35°C hold 5 min to 260°C at 20°C/min hold 2 min
Injector Temp: Cool-on-Column
Detector Temp: 325°C



Standard Solution

Analysis Method: GC/FID Headspace
Column: DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness
Temp Program: 40°C hold 12 min
Injector Temp: 200°C
Detector Temp: 250°C



COA Revision History

Revision No.	Date	Reason for Revision
00	May 10, 2023	Initial version.

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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-200

Ethyl alcohol

Catalog Number:	E-032
Solution Lot:	FN03132302
Expiration:	March 2028
Diluent:	Water
Volume per Ampule:	1.2 mL
Storage:	Refrigerate (Do Not Freeze)
Country of Origin:	Canada
Intended Use:	For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- For quantitative applications, the minimum sample size for intended use is 100 µL.

Component	Solution Purity	Certified Concentration
Ethanol	> 99.9%	200 ± 1 mg/dL

- Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.249% and the relative expanded uncertainty is 0.50% at the 95% confidence interval (k=2).
- The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.
- Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.
- Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred.

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ANAB ANSI National Accreditation Board ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

April 14, 2023
Date

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- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

Standard Solution	Lot Number	Comparison to NIST Lot SRM 2895 mg/dL	Homogeneity % RSD
New Lot	FN03132302	199	1.3
Previous Lot	FN02052101	199	0.9
Acceptance Criteria		**± 2%**	**≤ 2**

- Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.
- The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.
- Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.
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Analyte Certification - Mass Balance Purity Factor

The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

Material Characterization Summary		
Analytical Test	**Method**	**Results**
Chromatographic Purity by GC/FID Analysis	20384346	> 99.9%
Residual Water Analysis by Karl Fischer Coulometry	20398075 [1]	0.09%
Mass Balance Purity Factor		99.90%

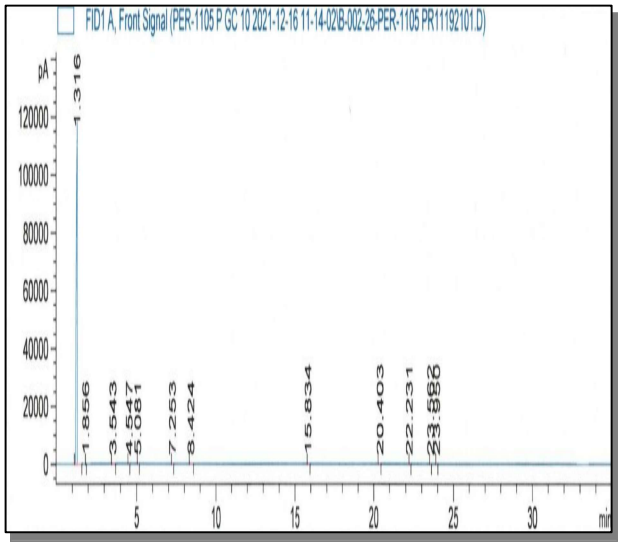
[1] Validated analytical method

- The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.

Spectral and Physical Data

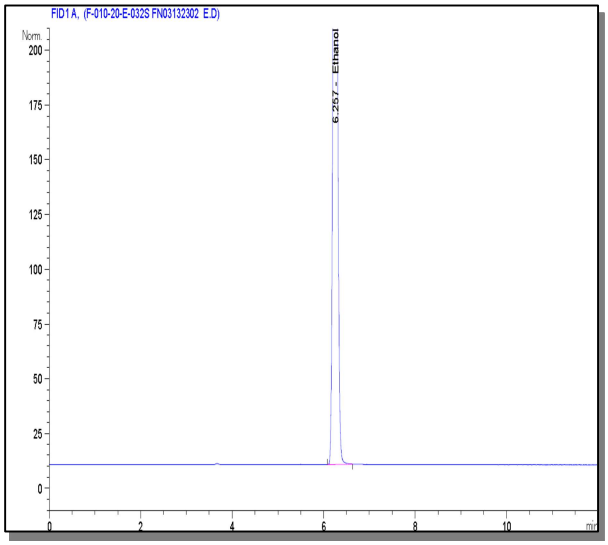
Neat Material

Analysis Method: GC/FID
Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness
Temp Program: 35°C hold 5 min to 100°C at 40°C/min
100°C to 280°C at 20°C/min
hold 8 min
Injector Temp: Cool-on-Column
Detector Temp: 325°C



Standard Solution

Analysis Method: GC/FID Headspace
Column: DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness
Temp Program: 40°C hold 12 min
Injector Temp: 200°C
Detector Temp: 250°C



COA Revision History

Revision No.	Date	Reason for Revision
00	April 14, 2023	Initial version.

The life science business of Merck KGaA, Darmstadt,
Germany operates as MilliporeSigma in the US and Canada.

Supelco®

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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-400

Ethyl alcohol

Catalog Number:	E-036
Solution Lot:	FN03052102
Expiration:	March 2026
Diluent:	Water
Volume per Ampule:	1.2 mL
Storage:	Refrigerate (Do Not Freeze)
Intended Use:	For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- For quantitative applications, the minimum sample size for intended use is 100 µL.

Component	Solution Purity	Certified Concentration
Ethanol	> 99.9%	400 ± 2 mg/dL

- Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.
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Darron Ellsworth, Quality Assurance Manager

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- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

Standard Solution	Lot Number	Comparison to NIST Lot SRM 2896 mg/dL	Homogeneity % RSD
New Lot	FN03052102	397	0.8
Previous Lot	FN10051906	400	1.7
Acceptance Criteria		**± 2%**	**≤ 2**

- Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.
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The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

Material Characterization Summary		
Analytical Test	**Method**	**Results**
Chromatographic Purity by GC/FID Analysis	SP10-0101	99.9%
Residual Water Analysis by Karl Fischer Coulometry	AM1346 [1]	0.11%
Mass Balance Purity Factor		99.81%

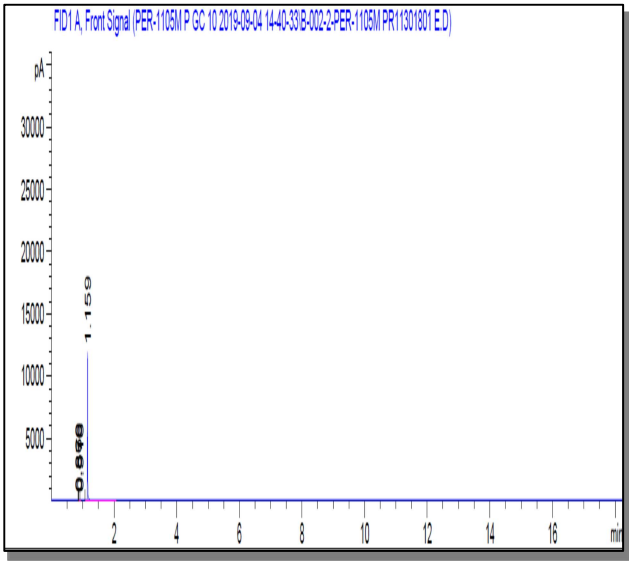
[1] Validated analytical method

- The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.

Spectral and Physical Data

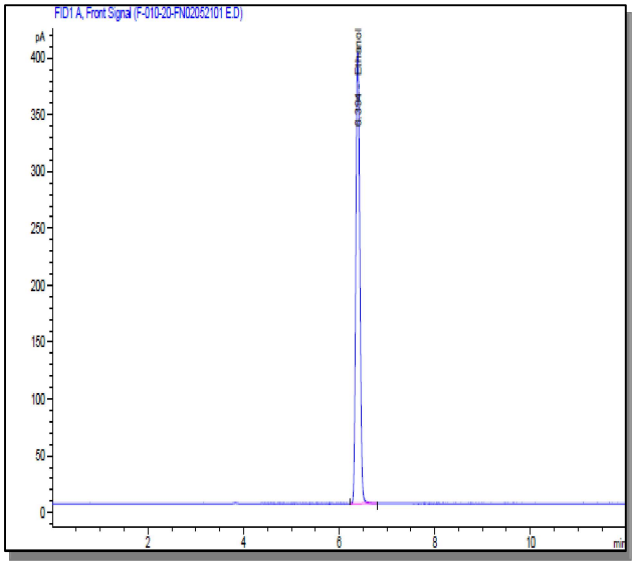
Neat Material

Analysis Method: GC/FID
Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness
Temp Program: 35°C hold 5 min to 260°C at 20°C/min hold 2 min
Injector Temp: Cool-on-Column
Detector Temp: 325°C



Standard Solution

Analysis Method: GC/FID Headspace
Column: DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness
Temp Program: 40°C hold 12 min
Injector Temp: 200°C
Detector Temp: 250°C



COA Revision History

Revision No.	Date	Reason for Revision
00	April 14, 2021	Initial version.

Art. No: **ETH-400-1ML**
Lot No: **12052023-B**
Expiry Date: **May 2028**
CoA No: **QC-COA-ETH-400-12052023-B.1**

Certificate of Analysis

Certified Reference Material

Aqueous Ethanol Standard Solution 400 mg/dL

Description	Ethanol diluted in Water 400 mg EtOH / dL Water (0.400 % by mass) 1 mL / ampoule
Certified Concentration	**Ethanol 400.0 mg/dL ± 0.209 mg/dL**

Expanded uncertainty of the certified concentration is in accordance with ISO/IEC 17025 at the 95% confidence interval using a coverage factor of k=2.

Metrological traceability

The certified reference material was produced in own facilities by weight of used solvent on calibrated balance(s) and traceable, following ISO/IEC 17025 guideline, to SI units.

The expanded uncertainty has been calculated and incorporates the following contributors:

- Mass of the solvent(s), including the calibration and repeatability uncertainties of the balance.
- Purity of the solvent(s), measured on pure solvent(s) including water content and GC/FID purity.
- Volume of the dilution, including uncertainties of volumetric measurement and temperature effects.

Procedure

The pure solvent is weighed into a volumetric flask, further diluted and the procedure is temperature monitored. The resulting dilution is filled into ampoules with a sufficient excess to allow complete volume withdrawal of the above given volume.

Homogeneity of the solution for the dilution of small amounts into a suitable diluent is ensured through adequate production conditions and therefore excluded from the uncertainty calculation.

Stability is ensured through real time stability studies on concentrations between 10 mg/dL and 700 mg/dL and found negligible inside the limits of the used analytical method and is therefore excluded from the uncertainty calculation.

Intended Use

The product is intended to be used for chromatographic analytic methods.

For analytical purposes only – not for human or animal use!

Storage Conditions

Store unopened below 30°C protected from light. Do not freeze. Opened ampoules must be used up in between 24 hours.

Lipomed certifies and warrants that this product conforms to the specifications stated in this certificate under the above storage conditions until its expiry date.

This certificate is issued electronically by Dr. L. Prévot (*Responsible Person Reference Materials*) on 21-Jun-2023 at Arlesheim and valid without signature.

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Art. No: **ETH-400-1ML**
Lot No: **12052023-B**
Expiry Date: **May 2028**
CoA No: **QC-COA-ETH-400-12052023-B.1**

Information on used solvent(s)

Name:	Ethanol
Mol Weight:	46.07 g/mol
CAS number:	64-17-5
Purity:	100.0 %
Water content:	0.01 %

The control is based on GC/FID and Karl-Fischer-Titration.

History (CoA)

Version	Change	Date
001	New version	21-Jun-2023

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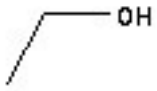
Certificate of Analysis
Certified Reference Material

Description: 40 mg/dL Aqueous Ethanol Standard Solution 1 mL

Lot No.: 518018 Expiration Date: 3/20/2027

Catalog No.: ETH-040-1ML Original issue date: 3/20/2024

Bulk Product Information: ethanol



Chemical Formula:	C2H6O
CAS Registry No:	64-17-5
Water Content:	<1%

Certified Values:

The certified value is based on gravimetric and volumetric preparation of this CRM. This CRM has been confirmed by gas chromatography (GC) or gas chromatograph/mass spectrometry (GC/MS) using an internally developed method against an independent source. The uncertainty value is calculated for a 95% confidence interval with a *k* value of 2.

Compound	CAS No.	Purity (%)	Neat Material Lot No.	Concentration, mg/dL
ethanol	64-17-5	99.9	202.9.7P	39.96 ± .47

Packaging and Storage:

The solution should be stored according to the following storage requirements: 4ºC +/- 4ºC
Once the product is opened, it should be transferred to a vial with minimum head space if the product was in a seal ampule.
Once opened, the expiration is determined by user specifications.

FOR ANALYTICAL PURPOSES ONLY: NOT FOR HUMAN OR ANIMAL USE!

Intended Uses:

This Certified Reference material (CRM) is intended for use as a calibration standard or a quality control standard for Chromatography Equipment such as GC, GC/MS, HPLC, and HPLC/MS. It may aslo be used for various USEPA, NIOSH, EN, ISO, EPA and ASTM methods.

Recommended storage container for ampuled products after opening is a 12mmx32mm amber vial with screw cap Teflon

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lined silicon septum. The modeled % change per day can be calculated using the following:

$$\% \text{ Change} = (-0.018\ln(x+31) + 0.1157) + 636.54y^{-3.202}$$

where x = boiling point of the most volatile analyte in the mix (degrees K)
y = boiling point of the solvent (degrees K)

This model assumes the container is stored at -10 °C and is unopened during storage. The user should determine what the acceptable error for their process is and calculate the maximum number of days the opened ampule should be stored.

NIST Standard Solutions for Concentration Verification:

Solution	Concentration
Reference 1 (NIST 2892)	39.00 mg/dL
Reference 2 (NIST 2893a)	76.63 mg/dL

Position of Samples	Concentration (mg/dL)
Start	41.0
Middle	41.2
End	41.0

Concentration Verification/ Lot to Lot Consistency (HPLC analysis):

Standard Solution	Lot Number	Concentration mg/dL (+/- 2%) Compared to NIST SRM 2892, 2893a	Ampule to Ampule Consistency (<3%)
Actual Lot	518018	41.1	0.8
Previous lot	N/A		

Random replicate samples of the final packaged CRM have been analyzed to prove homogeneity in accordance with internal procedure O2-QS-011. This is consistent with the intended use of this CRM. The homogeneity of this product has been confirmed by procedures consistent with ISO/IEC 17025:2017 and ISO 17034:2016.

Supportive Data:

Parameter	Specification	Result
Appearence	Clear / colorless	Conforms
Identity	HPLC analysis Rt corresponds to Rt of reference standard (+/- 0.5 min)	Conforms
Solution Purity	Ethanol, HPLC >99%	Conforms
Solvent Purity	Water, HPLC grade	Conforms
Extractable Volume	> 1 mL	Conforms

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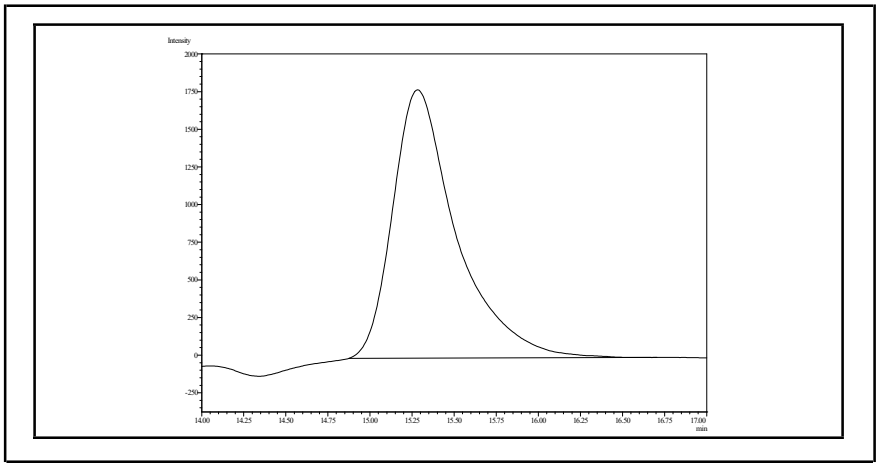
Chromatography:



Method Conditions:

Instrument
HPLC/RID

Detection
RID

Column/Flow
Phenomenex Rezex ROA - Organic Acid H+ (8%) 300mm x 7.8mm ID / 0.8 mL/min

Method Details
0.005 N H2SO4

Isocratic

Inj.-Vol
10 µL

General Information:

Accreditation:

This CRM was manufactured by an ISO 17025:2017 chemical testing lab (Certificate number 3031.01) and ISO 17034:2016 Reference Material Producer (Certificate number 3031.02) accredited by The American Association of Laboratory Accreditation (A2LA).

Expiration Information:

The stability of this product is based upon rigorous short term and long term testing of the solution for the certified value. These tests include the effect of temperature and packaging on the product. This standard is guaranteed until the following date: 20-Mar-2027

Method of Preparation:

All weights are traceable through N. I. S. T. Test No. 822/264157-00. Concentration (correct for purity) and uncertainty (95% confidence) values listed are determined gravimetricly.

Glassware Calibration:

Only Class A glassware is used in the manufacture and quality control of Standards. All glassware is calibrated using NIST traceable weights.

Calculation of Uncertainty:

The following equations are used to calculate the value of the expanded uncertainty: $u=ku_c$: u=Expanded Uncertainty, k= the coverage factor at the 95% confidence level, k=2, u_c = the combined uncertainty $u_c = \sqrt{\sum u_i^2}$ where u_i are the individual uncertainty components for characterization, transportation, homogeneity, and shelf life.

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Weights and Balance Calibration:

Weights used perform daily checks on balances calibrated annually by the State of South Carolina Department of Agriculture Metrology Laboratory and are traceable to N.I.S.T. Balances are checked daily in accordance to in house procedure O2-LB-G-002. Balances are calibrated annually by an ISO/IEC 17025:2017 and ISO 17034:2016 accredited metrology service.

Hazardous Information:

Refer to MSDS

Manufactured By:	Certified By:	Released By:
Shane Overcash	Elizabeth Ford	Susan Mathews
Team Leader, Semi-Volatiles	**Quality Control Chemist III**	**Quality Control Team Lead**

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The producer of this reference material is registered to ISO 9001:2015 under 56 100 19560019 by TUV USA and accredited to ISO 17025:2017 and ISO 17034:2016 by A2LA with the certification numbers 3031.01 and 3031.02.

ISO Guide 34 Accredited
Reference Material Producer
Cert. No. 3031.02

EtOH WH 2,0 g/L – In vitro diagnosticum

Ethanolkontrollen im Vollblut

Anwendung
Die Probe ist als Richtigkeitskontrolle oder Kalibrator für die Ethanolbestimmung einsetzbar.

Gebrauchsanweisung
Die Probe ist gebrauchsfertig und entsprechend der eigenen Laborvorschriften einzusetzen.

Zielwert
Die Zielwerte wurden unter der organisatorischen Leitung der ARVECON GmbH im Rahmen ihres Ringversuchsprogramms im Ringversuch EtB 2/24 B – Ethanol in Vollblut bestimmt. Die Analysen wurden von den Teilnehmern mit GC durchgeführt. Die Zielwerte wurden durch die Ringversuchsleitung der ARVECON freigegeben.

Lagerung und Haltbarkeit
Lagerung: + 2 °C bis + 8 °C
Haltbarkeit:
- Original verschlossen, lichtgeschützt: siehe Verfallsdatum auf der Packung.
- Dicht verschlossen, lichtgeschützt: siehe Verfallsdatum auf der Packung.

Vorsichtsmaßnahmen
Alle Materialien humanen Ursprungs sind grundsätzlich mit derselben Sorgfalt wie potentiell infektiöse Patientenproben zu behandeln.
Jede zur Herstellung verwendete Bluteinheit wurde auf Antigen und Antikörper geprüft und für negativ befunden: HBsAG, anti-HIV-1, anti-HIV-2, anti-HBc und anti-HCV.

EtOH WH 2.0 g/L – For in vitro diagnostic use

Ethanol control in whole blood

Application
This material should be used in accordance with the laboratory´s operating procedures for instrument calibration or as a control material

User guide
This ACQ Science EtOH WH requires no additional preparation and is ready for use.

Target value
This material was tested in the proficiency test EtB 2/24 B – Ethanol in whole blood, organized by ARVECON GmbH. The target values listed are the consensus values obtained from this trial. Quantitative analyses were performed by the participants using Gas Chromatography. The target values were released by the coordinator of proficiency testing of ARVECON.

Storage and stability
Storage: + 2 °C to + 8 °C
Stability:
- Sealed container, stored in the dark: see expiration date on the package.
- Stored in the dark tightly capped: see expiration date on package.

Precautions
All materials of human origin should be considered as potentially infectious and treated with the same care as patient specimens.
Each individual blood unit used for the production of the control was tested for the following antigens and antibodies: HBsAG, anti-HIV-1, anti-HIV-2, anti-HBc and anti-HCV and found to be negative.

Ch.-B / Lotto:	4130622206
Best.-Nr. / Codice:	WH20-015 (10 x 1,5 mL) WH20-115 (100 x 1,5 mL) WH20-030 (10 x 3,0 mL)
FG.Nr:	24-08
Version / Versione:	2 – 202407

Lot / Lot:	4130622206
Best.-Nr. / Codice:	WH20-015 (10 x 1.5 mL) WH20-115 (100 x 1.5 mL) WH20-030 (10 x 3.0 mL)
FG.Nr:	24-08
Version / Versione:	2 – 202407

EtOH WH 2,0 g/L – Uso diagnostico in vitro

Controllo d'etanolo in sangue intero

Applicazione
Utilizzabile nelle procedure definite da ciascun laboratorio come calibratore o come materiale di controllo.

Utilizzo
Pronto all'uso.

Valori attesi
I valori attesi sono stati assegnati tramite l'attività di proficiency test della ARVECON: "EtB 2/24 B – Ethanol in sangue intero" sotto la direzione organizzativa di ARVECON GmbH. Le analisi sono state eseguite dai partecipanti tramite GC. I valori attesi sono stati forniti dal coordinatore dell'attività di proficiency test del ARVECON.

Conservazione e stabilità
Conservazione: + 2 °C fino a + 8 °C
Stabilità:
- Flacone non aperto: se conservato ben chiuso ed al riparo dalla luce fino alla data di scadenza.
- Flacone aperto: se conservato ben chiuso ed al riparo dalla luce fino alla data di scadenza in etichetta.

Precauzioni
Tuttavia, poiché nessuna analisi può offrire sicurezza completa che gli agenti infettivi siano assenti, questo prodotto deve essere manipolato osservando le stesse precauzioni di sicurezza usate quando si manipola qualunque tipo di materiale potenzialmente infettivo.
I componenti originari da cui questo prodotto è stato derivato, sono stati trovati negativi per HBsAg e per gli anticorpi contro HCV, HBc, HIV-1 e HIV-2 attraverso metodologie di analisi approvate.

EtOH WH 2,0 g/L – Usage in vitro

Contrôle d'éthanol dans le sang total

Application
Standard dédié à la calibration pour techniques analytiques de détermination de concentration d'éthanol ou à utiliser comme contrôle d'exactitude.

Utilisation
Ce contrôle est prêt à l'emploi.

Valeur cible
Les valeurs cibles ont été déterminées lors d'un test inter-laboratoire de ARVECON: 'EtB 2/24 B – Ethanol dans le sang total', organisé par la société ARVECON GmbH. Les participants ont utilisé la méthode GC. Les valeurs cibles ont été validées par le responsable des tests inter-laboratoires de ARVECON.

Conservation et stabilité
Conservation: + 2 °C jusqu'à + 8 °C
Stabilité:
- Scellé (à l'origine), à l'abri de la lumière: voire la date d'expiration indiquée sur l'étiquette.
- à stocker hermétiquement à l'abri de la lumière: voire la date d'expiration indiquée sur l'étiquette.

Précautions
Tout
infecti
patien
Chaqu
testée
anti-H

Hersteller / Manufacturer / Produttore / Producteur

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Germany

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Fax: + 49 (0) 7457 94
E-mail: info@acq-scie

IVD 10 x 1,5 ml (liq.) REF WH20-015

EtOH Check WH 2,0 g/l

Ethanolkontrolle im Vollblut

Ethanol control in whole blood

Contrôle d'éthanol dans le sang total

LOT 4130622206/10 2029-05 2°C 8°C CE

ACQ Science GmbH
Etzwiesenstraße 37
72108 Rottenburg
Germany

EtOH WH 2,0 g/L – Lot: 4130622206 - For in vitro diagnostic use

Ethanol control in whole blood

Messverfahren Method Metodo Méthode	Zielwert Target value Valori attesi Valeur cible	Konfidenzbereiche / Confidence ranges / Intervallo di fiducia / Intervalle de confiance			Einheit Unit Unità Unité
		statistisch / statistical[1] statistico / statistique[1]	forensisch / forensic[2] forense /medicine légale[2]	klinisch / clinical[3] clinico / clinique[3]	
GC	1,963	1,821– 2,105	1,865 – 2,061	1,786 – 2,140	g/L

[1] Konfidenzbereich – Analysenwerte

Der Konfidenzbereich gibt den Bereich an, in dem der Zielwert mit einer Wahrscheinlichkeit von 95% liegt.

[2] Konfidenzbereich – Deutsche forensische Richtlinie

[EtOH] ≤ 1,06 g/L → Konfidenzbereich ± 0,053 g/L von dem Zielwert
[EtOH] > 1,06 g/L → Konfidenzbereich ± 5% von dem Zielwert

Literatur:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

[3] Konfidenzbereich – Richtlinie der deutschen Bundesärztekammer

Für 0,2 < [EtOH] ≤ 0,6 g/L → Konfidenzbereich ± 15% vom Zielwert
Für 0,6 < [EtOH] ≤ 5,0 g/L → Konfidenzbereich ± 9% vom Zielwert

Literatur:
Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

[1] Confidence ranges – measured values

The confidence interval indicates the range in which the target value is located with a significance level of 95%.

[2] Confidence ranges – German forensic directives

[EtOH] ≤ 1.06 g/L→ ± 0.053 g/L from the target value
[EtOH] > 1.06 g/L → ± 5% from the target value

References:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

[3] Confidence ranges – Directive of the German Medical Association

0.2 < [EtOH] ≤ 0.6 g/L → ± 15% from the target value
0.6 < [EtOH] ≤ 5.0 g/L → ± 9% from the target value

References:
Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

[1] Intervallo di fiducia - Valori di analisi

L'intervallo di fiducia indica l'intervallo entro il quale si trova il valore atteso con un livello di significatività del 95%.

[2] Intervallo di fiducia – Direttiva Forense Tedesca

[EtOH] ≤ 1,06 g/L → ± 0,053 g/L del valore atteso
[EtOH] > 1,06 g/L → ± 5% del valore atteso

Bibliografia:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestim-mung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

[3] Intervallo di fiducia – Direttiva dell' Ordine Nazionale Tedesca dei Medici

0,2 < [EtOH] ≤ 0,6 g/L → ± 15% del valore atteso
0,6 < [EtOH] ≤ 5,0 g/L → ± 9% del valore atteso

Bibliografia:
Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

[1] Intervalle de confiance – Valeurs des analyses

La marge de confiance est la marge dans laquelle la valeur cible se trouve avec une probabilité de 95%.

[2] Intervalle de confiance – Directives allemandes de la Médecine Légale

[EtOH] ≤ 1,06 g/L → ± 0,053 g/L de la valeur cible
[EtOH] > 1,06 g/L → ± 5% de la valeur cible

Littérature:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestim-mung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

[3] Intervalle de confiance – Directives allemandes cliniques

0,2 < [EtOH] ≤ 0,6 g/L → ± 15% de la valeur cible
0,6 < [EtOH] ≤ 5,0 g/L → ± 9% de la valeur cible

Littérature:
Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

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E-mail: info@acq-science.de

CE

EtOH WH 1,1 g/L – In vitro diagnosticum

Ethanolkontrollen im Vollblut

Anwendung
Die Probe ist als Richtigkeitskontrolle oder Kalibrator für die Ethanolbestimmung einsetzbar.

Gebrauchsanweisung
Die Probe ist gebrauchsfertig und entsprechend der eigenen Laborvorschriften einzusetzen.

Zielwert
Die Zielwerte wurden unter der organisatorischen Leitung der ARVECON GmbH im Rahmen des Ringversuchprogramms der GTFCh im Ringversuch EtB 3/20 - EtOH in Vollblut bestimmt. Die Analysen wurden von den Teilnehmern mit GC durchgeführt. Die Zielwerte wurden durch die Ringversuchsleitung der GTFCh freigegeben.

Lagerung und Haltbarkeit
Lagerung: + 2° bis + 8° C
Haltbarkeit:
- Original verschlossen, lichtgeschützt: siehe Verfallsdatum auf der Packung.
- Dicht verschlossen, lichtgeschützt: siehe Verfallsdatum auf der Packung.

Vorsichtsmaßnahmen
Alle Materialien humanen Ursprungs sind grundsätzlich mit derselben Sorgfalt wie potentiell infektiöse Patientenproben zu behandeln.
Jede zur Herstellung verwendete Bluteinheit wurde auf Antigen und Antikörper geprüft und für negativ befunden: HBsAG, anti-HIV-1, anti-HIV-2, anti-HBc und anti-HCV.

EtOH WH 1,1 g/L – For in vitro diagnostic use

Ethanol control in whole blood

Application
This material should be used in accordance with the laboratory´s operating procedures for instrument calibration or as a control material

User guide
This ACQ Science EtOH WH requires no additional preparation and is ready for use.

Target value
This material was tested in the proficiency test EtB 3/20 - EtOH in whole blood, organized for the GTFCh by ARVECON GmbH. The target values listed are the consensus values obtained from this trial. Quantitative analyses were performed by the participants using Gas Chromatography. The target values were released by the coordinator of proficiency testing of the GTFCh.

Storage and stability
Storage: + 2 ° to + 8 ° C
Stability:
- Sealed container, stored in the dark: see expiration date on the package.
- Stored in the dark tightly capped: see expiration date on package.

Precautions
All materials of human origin should be considered as potentially infectious and treated with the same care as patient specimens.
Each individual blood unit used for the production of the control was tested for the following antigens and antibodies: HBsAG, anti-HIV-1, anti-HIV-2, anti-HBc and anti-HCV and found to be negative.

Ch.-B / Lotto:	4100620181
Best.-Nr. / Codice:	WH11-015 (10 x 1,5 ml) WH11-115 (100 x 1,5 ml) WH11-030 (10 x 3,0 ml)
GTFCh-FG.Nr:	20-14
Version / Versione:	2 – 202207

Lot / Lot:	4100620181
Best.-Nr. / Codice:	WH11-015 (10 x 1,5 ml) WH11-115 (100 x 1,5 ml) WH11-030 (10 x 3,0 ml)
GTFCh-FG.Nr:	20-14
Version / Versione:	2 – 202207

EtOH WH 1,1 g/L – Uso diagnostico in vitro

Controllo d'etanolo in sangue intero

Applicazione
Utilizzabile nelle procedure definite da ciascun laboratorio come calibratore o come materiale di controllo.

Utilizzo
Pronto all'uso.

Valori attesi
I valori attesi sono stati assegnati tramite l'attività di proficiency test della Società Tedesca di Tossicologia e Chimica Forense (GTFCh) " EtB 3/20 – *Ethanol in sangue intero"* sotto la direzione organizzativa di ARVECON GmbH. Le analisi sono state eseguite dai partecipanti tramite GC. I valori attesi sono stati forniti dal coordinatore dell'attività di proficiency test del GTFCh.

Conservazione e stabilità
Conservazione: + 2° fino a + 8° C
Stabilità:
- Flacone non aperto: se conservato ben chiuso ed al riparo dalla luce fino alla data di scadenza.
- Flacone aperto: se conservato ben chiuso ed al riparo dalla luce fino alla data di scadenza in etichetta.

Precauzioni
Tuttavia, poiché nessuna analisi può offrire sicurezza completa che gli agenti infettivi siano assenti, questo prodotto deve essere manipolato osservando le stesse precauzioni di sicurezza usate quando si manipola qualunque tipo di materiale potenzialmente infettivo.
I componenti originari da cui questo prodotto è stato derivato, sono stati trovati negativi per HBsAg e per gli anticorpi contro HCV, HBc, HIV-1 e HIV-2 attraverso metodologie di analisi approvate.

EtOH WH 1,1 g/L – Usage in vitro

Contrôle d'éthanol dans le sang total

Application
Standard dédié à la calibration pour techniques analytiques de détermination de concentration d'éthanol ou à utiliser comme contrôle d'exactitude.

Utilisation
Ce contrôle est prêt à l'emploi.

Valeur cible
Les valeurs cibles ont été déterminées lors d'un test inter-laboratoire de l'Association Allemande de Toxicologie et de Médecine Légale (GTFCh) 'EtB 3/20 – *Ethanol dans le sang total*, organisé par la société ARVECON GmbH. Les participants ont utilisé la méthode GC. Les valeurs cibles ont été validées par le responsable des tests inter-laboratoires de la GTFCh.

Conservation et stabilité
Conservation: + 2° jusqu'à + 8° C
Stabilité:
- Scellé (à l'origine), à l'abri de la lumière: voire la date d'expiration indiquée sur l'étiquette.
- à stocker hermétiquement à l'abri de la lumière: voire la date d'expiration indiquée sur l'étiquette.

Précautions
Tout matériel humain doit être considéré comme étant potentiellement infectieux et traité dans les mêmes conditions que des échantillons de patients.
Chaque unité de sang utilisée pour la préparation de ce contrôle a été testée et trouvée négatif pour les antigènes et anticorps suivants: AgHbS, anti-HIV-1, anti-HIV-2, anti-HBc et anti-HCV.

Hersteller / Manufacturer / Produttore / Producteur

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CE

EtOH WH 1,1 g/L – Lot: 4100620181 - For in vitro diagnostic use

Ethanol control in whole blood

Messverfahren Method Metodo Méthode	Zielwert Target value Valori attesi Valeur cible	Konfidenzbereiche / Confidence ranges / Intervallo di fiducia / Intervalle de confiance			Einheit Unit Unità Unité
		statistisch / statistical[1] statistico / statistique[1]	forensisch / forensic[2] forense /medicine légale[2]	klinisch / clinical[3] clinico / clinique[3]	
GC	1,10	1,04 – 1,16	1,045 – 1,155	1,001 – 1,199	g/L

[1] Konfidenzbereich – Analysenwerte

Der Konfidenzbereich gibt den Bereich an, in dem der Zielwert mit einer Wahrscheinlichkeit von 95% liegt.

[2] Konfidenzbereich – Deutsche forensische Richtlinie

[EtOH] ≤ 1,06 g/L → Konfidenzbereich ± 0,053 g/L von dem Zielwert
[EtOH] > 1,06 g/L → Konfidenzbereich ± 5% von dem Zielwert

Literatur:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)
DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke – VA 0900-54 Version1

[3] Konfidenzbereich – Richtlinie der deutschen Bundesärztekammer

Für 0,2 < [EtOH] ≤ 0,6 g/L → Konfidenzbereich ± 15 % vom Zielwert
Für 0,6 < [EtOH] ≤ 5,0 g/L → Konfidenzbereich ± 9 % vom Zielwert

Literatur:
Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (15.02.2008)

[1] Confidence ranges – measured values

The confidence interval indicates the range in which the target value is located with a significance level of 95%.

[2] Confidence ranges – German forensic directives

[EtOH] ≤ 1.06 g/L→ ± 0.053 g/L from the target value
[EtOH] > 1.06 g/L → ± 5% from the target value

References:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)
DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke – VA 0900-54 Version1

[3] Confidence ranges – Directive of the German Medical Association

0.2 < [EtOH] ≤ 0.6 g/L → ± 15 % from the target value
0.6 < [EtOH] ≤ 5.0 g/L → ± 9 % from the target value

References:
Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (15.02.2008)

[1] Intervallo di fiducia - Valori di analisi

L'intervallo di fiducia indica l'intervallo entro il quale si trova il valore atteso con un livello di significatività del 95%.

[2] Intervallo di fiducia – Direttiva Forense Tedesca

[EtOH] ≤ 1,06 g/L → ± 0,053 g/L del valore atteso
[EtOH] > 1,06 g/L → ± 5% del valore atteso

Bibliografia:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)
DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke – VA 0900-54 Version1

[3] Intervallo di fiducia – Direttiva dell' Ordine Nazionale Tedesca dei Medici

0,2 < [EtOH] ≤ 0,6 g/L → ± 15 % del valore atteso
0,6 < [EtOH] ≤ 5,0 g/L → ± 9 % del valore atteso

Bibliografia:
Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (15.02.2008)

[1] Intervalle de confiance – Valeurs des analyses

La marge de confiance est la marge dans laquelle la valeur cible se trouve avec une probabilité de 95%.

[2] Intervalle de confiance – Directives allemandes de la Médecine Légale

[EtOH] ≤ 1,06 g/L → ± 0,053 g/L de la valeur cible
[EtOH] > 1,06 g/L → ± 5% de la valeur cible

Littérature:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)
DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke – VA 0900-54 Version1

[3] Intervalle de confiance – Directives allemandes cliniques

0,2 < [EtOH] ≤ 0,6 g/L → ± 15 % de la valeur cible
0,6

Lit
Ric
tori

GI_EtOHWH_11_4100620181_20220720

IVD 10 x 1,5 ml (liq.) REF WH11-015

EtOH Check WH 1,1 g/l

Ethanolkontrolle im Vollblut

Ethanol control in whole blood

Contrôle d'éthanol dans le sang total

LOT 4100620181/7 2029-05 2°C 8°C CE

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SERVICES TO HEALTH

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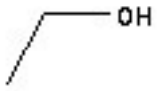
Certificate of Analysis
Certified Reference Material

Description: 100 mg/dL Aqueous Ethanol Standard Solution 1 mL
0.100% by mass

Lot No.: 517758 Expiration Date: 2/7/2027

Catalog No.: ETH-100-1ML Original issue date: 2/7/2024

Bulk Product Information: ethanol



Chemical Formula:	C2H6O
CAS Registry No:	64-17-5
Water Content:	<1%

Certified Values:

The certified value is based on gravimetric and volumetric preparation of this CRM. This CRM has been confirmed by gas chromatography (GC) or gas chromatograph/mass spectrometry (GC/MS) using an internally developed method against an independent source. The uncertainty value is calculated for a 95% confidence interval with a *k* value of 2.

Compound	CAS No.	Purity (%)	Neat Material Lot No.	Concentration, mg/dL
ethanol	64-17-5	99.9	202.9.7P	100.2 ± 1.6

Packaging and Storage:

The solution should be stored according to the following storage requirements: 4ºC +/- 4ºC
Once the product is opened, it should be transferred to a vial with minimum head space if the product was in a seal ampule.
Once opened, the expiration is determined by user specifications.

FOR ANALYTICAL PURPOSES ONLY: NOT FOR HUMAN OR ANIMAL USE!

Intended Uses:

This Certified Reference material (CRM) is intended for use as a calibration standard or a quality control standard for Chromatography Equipment such as GC, GC/MS, HPLC, and HPLC/MS. It may aslo be used for various USEPA, NIOSH, EN, ISO, EPA and ASTM methods.

Recommended storage container for ampuled products after opening is a 12mmx32mm amber vial with screw cap Teflon

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lined silicon septum. The modeled % change per day can be calculated using the following:

$$\% \text{ Change} = (-0.018\ln(x+31) + 0.1157) + 636.54y^{-3.202}$$

where x = boiling point of the most volatile analyte in the mix (degrees K)
y = boiling point of the solvent (degrees K)

This model assumes the container is stored at -10 °C and is unopened during storage. The user should determine what the acceptable error for their process is and calculate the maximum number of days the opened ampule should be stored.

NIST Standard Solutions for Concentration Verification:

Solution	Concentration
Reference 1 (NIST 2892)	39.00 mg/dL
Reference 2 (NIST 2893a)	76.63 mg/dL

Position of Samples	Concentration (mg/dL)
Start	102.1
Middle	101.6
End	102.2

Concentration Verification/ Lot to Lot Consistency (HPLC analysis):

Standard Solution	Lot Number	Concentration mg/dL (+/- 2%) Compared to NIST SRM 2892, 2893a	Ampule to Ampule Consistency (<3%)
Actual Lot	517758	102.0	0.5
Previous lot	N/A		

Random replicate samples of the final packaged CRM have been analyzed to prove homogeneity in accordance with internal procedure O2-QS-011. This is consistent with the intended use of this CRM. The homogeneity of this product has been confirmed by procedures consistent with ISO/IEC 17025:2017 and ISO 17034:2016.

Supportive Data:

Parameter	Specification	Result
Appearence		Conforms
Identity	HPLC analysis Rt corresponds to Rt of reference standard (+/- 0.5 min)	Conforms
Solution Purity	Ethanol, HPLC >99%	Conforms
Solvent Purity	Water, HPLC grade	Conforms
Extractable Volume	> 1 mL	Conforms

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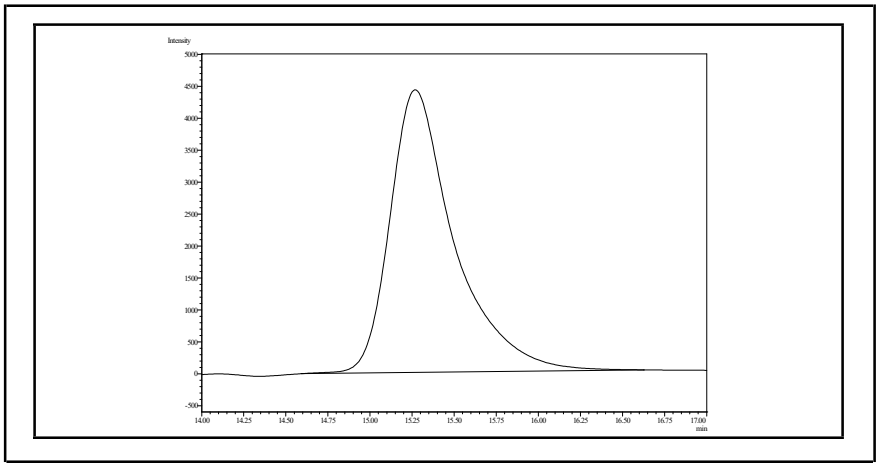
Chromatography:



Method Conditions:

Instrument
HPLC/RID

Detection
RID

Column/Flow
Phenomenex Rezex ROA - Organic Acid H+ (8%) 300mm x 7.8mm ID / 0.8 mL/min

Method Details
0.005 N H2SO4

Isocratic

Inj.-Vol
10 µL

General Information:

Accreditation:

This CRM was manufactured by an ISO 17025:2017 chemical testing lab (Certificate number 3031.01) and ISO 17034:2016 Reference Material Producer (Certificate number 3031.02) accredited by The American Association of Laboratory Accreditation (A2LA).

Expiration Information:

The stability of this product is based upon rigorous short term and long term testing of the solution for the certified value. These tests include the effect of temperature and packaging on the product. This standard is guaranteed until the following date: 7-Feb-2027

Method of Preparation:

All weights are traceable through N. I. S. T. Test No. 822/264157-00. Concentration (correct for purity) and uncertainty (95% confidence) values listed are determined gravimetricly.

Glassware Calibration:

Only Class A glassware is used in the manufacture and quality control of Standards. All glassware is calibrated using NIST traceable weights.

Calculation of Uncertainty:

The following equations are used to calculate the value of the expanded uncertainty: $u=ku_c$: u=Expanded Uncertainty, k= the coverage factor at the 95% confidence level, k=2, u_c = the combined uncertainty $u_c = \sqrt{\sum u_i^2}$ where u_i are the individual uncertainty components for characterization, transportation, homogeneity, and shelf life.

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Weights and Balance Calibration:

Weights used perform daily checks on balances calibrated annually by the State of South Carolina Department of Agriculture Metrology Laboratory and are traceable to N.I.S.T. Balances are checked daily in accordance to in house procedure O2-LB-G-002. Balances are calibrated annually by an ISO/IEC 17025:2017 and ISO 17034:2016 accredited metrology service.

Hazardous Information:

Refer to MSDS

Manufactured By:	Certified By:	Released By:
Shane Overcash	Elizabeth Ford	Susan Mathews
Team Leader, Semi-Volatiles	**Quality Control Chemist III**	**Quality Control Team Lead**

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The producer of this reference material is registered to ISO 9001:2015 under 56 100 19560019 by TUV USA and accredited to ISO 17025:2017 and ISO 17034:2016 by A2LA with the certification numbers 3031.01 and 3031.02.

ISO Guide 34 Accredited
Reference Material Producer
Cert. No. 3031.02