# Scottsdale Police Department Crime Laboratory

# Calibrators and Control Certificates for Samples Run

09/23/2024 -



# 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  $\mu$ L.

	Component	Solution Purity	Certified Concentration
	Ethanol	> 99.9%	20.00 ± 0.08 mg/dL
•	Uncertainty of the concentration, ex accordance with ISO 17025 and ISC k=2 and has been calculated by stat reference standards and incorporate measurement. The dispensing proce uncertainty calculations and is, there stability studies and is, therefore, ex	pressed in terms of volume, in 17034 at the 95% confidenc istical analysis of our product s uncertainty of the purity fac ss is sufficiently controlled as efore, excluded. Solution stab coluded.	s an expanded uncertainty in e interval using a coverage factor of ion methods applicable to ethanol ctor, material density and mass to not be a significant contributor to ility is established through real time

- 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.



Darron Ellsworth, Quality Assurance Manager

**July 27, 2021** Date

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### 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 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.

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

#### Solution Standard Concentration and Batch Homogeneity

- 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 <sup>1</sup>	0.11%	
Identity by GC/MS	SP10-0105	Consistent with Structure	
Mass Balance Purity Factor		99.81%	
<sup>1</sup> 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**



# COA Revision History

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

# 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.

Ethanol > 99.9%	$100.0 \pm 0.4 \text{ mg/dL}$	

- 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 the Canada.



Darron Ellsworth, Quality Assurance Manager

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Date



#### 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.

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

#### **Solution Standard Concentration and Batch Homogeneity**

- 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 <sup>1</sup>	0.16%	
Mass Balance Purity Factor		99.84%	
<sup>1</sup> 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		Standard Solution	on
Analysis Method:	GC/FID	Analysis Method:	GC/FID Headspace
Column:	DB-5ms, 30 m x 0.53 mm ID,	Column:	DB-ALC1 30 m x 0.53 mm ID,
	1.5 um film thickness		3.0 um film thickness
Temp Program	$35^{\circ}$ C hold 5 min to $260^{\circ}$ C at	Temp Program	$40^{\circ}$ C hold 12 min
remptrogram	$20^{\circ}$ C/min hold 2 min	Injector Temp:	
Inicator Tomas	Cool on Column	Detector Temp.	200 C
injector remp:		Detector Temp:	250°C
Detector Temp:	325°C		
FID1 A. (B-002-13-PER-1105S PR11192101	E D	FID1 A, Front Signal (F-010-10-FN03072301 E.D)	
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## COA Revision History

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



# 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.

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.





April 14, 2023

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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 <sup>1</sup>	0.09%	
Mass Balance Purity Factor		99.90%	

<sup>1</sup> 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**



## COA Revision History

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

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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.
- 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.
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Darron Ellsworth, Quality Assurance Manager

**April 14, 2021** 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 St	andard Conc	entration and	Batch Home	ogeneity

		Comparison to NIST	
Standard	Lot	Lot SRM 2896	Homogeneity
Solution	Number	mg/dL	% 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.
- 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.
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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	SP10-0101	99.9%	
Residual Water Analysis by Karl Fischer Coulometry	AM1346 <sup>1</sup>	0.11%	
Mass Balance Purity Factor		99.81%	
1 ye balana da sa da ga da sa da sa			

<sup>1</sup> 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



#### COA Revision History

<b>Revision No.</b>	Date	Reason for Revision
00	April 14, 2021	Initial version.

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Germany operates as MilliporeSigma in the US and Canada.





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.

www.lipomed.com

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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)

SERVICES

Name:	Ethanol
Mol Weight:	46.07 g/mo <b>l</b>
CAS number:	64-17-5
Purity:	100.0 %
Water content:	0.01 %
•. •	

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

TO HEALTH

#### History (CoA)

Version	Change	Date
001	New version	21-Jun-2023

LIPOMED AG Fabrikmattenweg 4 4144 Arlesheim Switzerland +41 61 702 02 00 (Phone) +41 61 702 02 20 (Fax)

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2/2



Page 1 of 4

# Certificate of Analysis Certified Reference Material

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

Lot No.: 518018 Catalog No.:ETH-040-1ML		Expiration Date: 3/20/2027 Original issue date: 3/20/2024
Bulk Product Information:	ethanol	
Chemical Formula:	C2H6O	он
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: 4°C +/- 4°C 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 also 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



## 150 Cambridge Park Drive Suite 705 Cambridge, MA 02140 +1 617-577-7222

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

% 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	Position of Samples	Concentration (mg/dL)
Reference 1	39.00 mg/dl	Start	41.0
(NIST 2892) Reference 2	55.00 mg/dE	Middle	41.2
(NIST 2893a)	76.63 mg/dL	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



Rev 2

# Chromatography:



# **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 gravimetriclly.

## 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:

Shane Overcash Team Leader, Semi-Volatiles

LGC Group 7290-B Investment Drive North Charleston, SC 29418 United States T | +1 843 763 4884 F | +1 866 509 5146 E | dr.ehrenstorfer@lgcgroup.com Certified By:

Elizabeth Ford Quality Control Chemist III

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. **Released By:** 

Season

Susan Mathews
Quality Control Team Lead



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 des Ringversuchprogramms der GTFCh im Ringversuch EtB 2/20 - 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.

Ch.-B / Lotto: Best.-Nr. / Codice:

GTFCh-FG.Nr: Version / Versione:  $\begin{array}{l} 4110320133\\ WH20-015 \ (10 \ x \ 1,5 \ ml)\\ WH20-115 \ (100 \ x \ 1,5 \ ml)\\ WH20-030 \ (10 \ x \ 3,0 \ ml)\\ 20-05 \\ 1-202006 \end{array}$ 

#### 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

Valori attesi sono stati assegnati tramite l'attività di proficiency test della Società Tedesca di Tossicologia e Chimica Forense (GTFCh) " EtB 2/20 – 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 seadenza 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.

Hersteller / Manufacturer / Produttore / Producteur

ACQ Science GmbH Etzwiesenstraße 37 72108 Rottenburg-Hailfingen Germany 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 2/20 - 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-HIV-2, anti-HIV-2, anti-HIV-2, and anti-HCV and found to be negative.

Lot / Lot: Best.-Nr. / Codice:

Version / Versione:

GTECh-EG.Nr:

4110320133 WH20-015 (10 x 1,5 ml) WH20-115 (100 x 1,5 ml) WH20-030 (10 x 3,0 ml) 20-05 1 - 202006

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 l'Association Allemande de Toxicologie et de Médecine Légale (GTFCh) 'EtB 2/20 – 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 lumiére: 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.

CE

1/2



#### EtOH WH 2.0 g/L - Lot: 4110320133 - For in vitro diagnostic use Ethanol control in whole blood

Messverfahren	Zielwert	Konfi	denzbereiche / Confidence rai	nges /	Einheit
Method	Target value	Interva	Ilo di fiducia / Intervalle de co	nfiance	Unit
Metodo	Valori attesi	statistisch / statistical <sup>1</sup>	forensisch / forensic <sup>2</sup>	klinisch / clinical <sup>3</sup>	Unità
Méthode	Valeur cible	statistico / statistique <sup>1</sup>	forense /medicine légale <sup>2</sup>	clinico / clinique <sup>3</sup>	Unité
GC	1,99	1,89 – 2,09	1,891 – 2,090	1,811 – 2,169	g/L

#### <sup>1</sup> Konfidenzbereich – Analysenwerte

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

<sup>2</sup> Konfidenzbereich – Deutsche forensische Richtlinie

 $[EtOH] \leq$  1,06  $\,$  g/L  $\rightarrow$  Konfidenzbereich  $\pm$  0,053 g/L von dem Zielwert [EtOH] > 1,06  $\,$  g/L  $\rightarrow$  Konfidenzbereich  $\pm$  5% von dem Zielwert References: Literatur: Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke. 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) (2011) 48: 137-143) DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke - VA 0900-54 Version1 <sup>3</sup> Konfidenzbereich – Richtlinie der deutschen Bundesärztekammer Für 0,2 < [EtOH] ≤ 0,6 g/L  $\rightarrow$  Konfidenzbereich ± 15 % vom Zielwert Für 0,6 < [EtOH]  $\leq$  5,0 g/L  $\rightarrow$  Konfidenzbereich ± 9 % vom Zielwert References: Literatur: Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (15.02.2008) <sup>1</sup> Intervallo di fiducia - Valori di analisi L'intervallo di fiducia indica l'intervallo entro il quale si trova il valore avec une probabilité de 95%. atteso con un livello di significatività del 95%. <sup>2</sup> Intervallo di fiducia - Direttiva Forense Tedesca  $\begin{array}{ll} [\text{EtOH}] \leq 1,06 & g/L \rightarrow \pm \, 0,053 \; g/L \; \text{del valore atteso} \\ [\text{EtOH}] > 1,06 & g/L \rightarrow \pm \, 5\% \; \text{del valore atteso} \end{array}$  $[EtOH] \le 1,06 \text{ g/L} \rightarrow \pm 0,053 \text{ g/L}$  de la valeur cible Littérature: Bibliografia: Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestim-mung für forensische Zwecke. 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) (2011) 48: 137-143) DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke - VA 0900-54 Version1

#### <sup>3</sup> Intervallo di fiducia – Direttiva dell' Ordine Nazionale Tedesca dei Medici

 $0.2 < [EtOH] \le 0.6 \text{ g/L} \rightarrow \pm 15 \%$  del valore atteso  $0.6 < [EtOH] \le 5.0 \text{ g/L} \rightarrow \pm 9 \%$  del valore atteso

#### Bibliografia:

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (15.02.2008)

GI EtOHWH\_20\_4110320133\_20200623

#### Hersteller / Manufacturer / Produttore / Producteur

**ACQ Science GmbH** Etzwiesenstraße 37 72108 Rottenburg-Hailfingen Germany

Tel.: + 49 (0) 7457 ! Fax: + 49 (0) 7457 E-mail: info@acq-s



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

<sup>2</sup> Confidence ranges – German forensic directives

[EtOH]  $\leq 1.06$  g/L $\rightarrow \pm 0.053$  g/L from the target value [EtOH] > 1.06 g/L  $\rightarrow \pm 5\%$  from the target value

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung

Richtlinicen 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

DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke - VA 0900-54 Version1

<sup>3</sup> Confidence ranges – Directive of the German Medical Association

 $0.2 < [EtOH] \le 0.6 \text{ g/L} \rightarrow \pm 15 \%$  from the target value  $0.6 < [EtOH] \le 5.0 \text{ g/L} \rightarrow \pm 9 \%$  from the target value

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (15.02.2008)

<sup>1</sup> Intervalle de confiance – Valeurs des analyses La marge de confiance est la marge dans laquelle la valeur cible se trouve

<sup>2</sup> Intervalle de confiance – Directives allemandes de la Médecine Légale

[EtOH] > 1,06 g/L  $\rightarrow \pm 5\%$  de la valeur cible

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestim-mung

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

DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke - VA 0900-54 Version1

<sup>3</sup> Intervalle de confiance – Directives allemandes cliniques

 $0.2 < [EtOH] \le 0.6 \text{ g/L} \rightarrow \pm 15 \%$  de la valeur cible  $0.6 < [EtOH] \le 5.0 \text{ g/L} \rightarrow \pm 9\%$  de la valeur cible

IVD 10 x 1,5 ml (liq.)

Litté

Rich

toriu

**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



ACQ Science GmbH

Etzwiesenstraße 37, 72108 Rottenburg-Hailfingen Germany, Tel. +49 (0) 7457 946 93-0



Page 1 of 4

# Certificate of Analysis Certified Reference Material

Description:	100 mg/dL A 0.100% by m	/dL Aqueous Ethanol Standard Solution 1 mL		
Lot No.: 517758			Expiration Date: 2/7/2027	
Catalog No.:ETH-10	00-1ML		Original issue date: 2/7/2024	
Bulk Product Inf	ormation:	ethanol		
Chemical Formula:		C2H6O	ОН	
CAS Registry No:		64-17-5	6	
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: 4°C +/- 4°C 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 also 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:

% 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	Position of Samples	Concentration (mg/dL)
Reference 1	39.00 mg/dl	Start	102.1
(NIST 2892) Reference 2	55.00 mg/dE	Middle	101.6
(NIST 2893a)	76.63 mg/dL	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



Rev 2

# Chromatography:



# **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 gravimetriclly.

## 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:

Shane Overcash Team Leader, Semi-Volatiles

LGC Group 7290-B Investment Drive North Charleston, SC 29418 United States T | +1 843 763 4884 F | +1 866 509 5146 E | dr.ehrenstorfer@lgcgroup.com **Certified By:** 

Elizabeth Ford Quality Control Chemist III

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. **Released By:** 

Season

Susan Mathews
Quality Control Team Lead



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