

VERMONT FORENSIC LABORATORY

TOXICOLOGY CASE SPECIFIC REVIEW CHECKLIST

Lot #: _____

AGENCY CASE #: Cerilliant FN12272201 ANALYST: SGS

LAB #: 0.010 Std Control Verification

BATCH FILES: 02122024 BAC

TECHNICAL REVIEWER: JSD DATE: 2/15/24

Blood Alcohol:

- Reported results are means of two or more replicates with two channel values each?
- All replicates for each sample within ± 5% from the calculated mean?
- %CV for all replicate values less than 5%?
- Internal standard peak areas within ± 20% of calibrators' average IS peak area?
- Surrogate compound concentrations between 0.900 to 1.100 g/100 ml?
- Correct MU value used?
- Data transcribed correctly and calculations verified*?

Blood Drug:

- Positive screening results passed on to correct confirmatory methods or reported as preliminary positive?
- Confirmation samples run within appropriate time frame in accordance with method-specific procedures?
- Confirm results and their associated uncertainties are reported to the correct number of significant figures?
- Sample analysis date for each method is consistent with the batch file?
- Reporting limits and analysis summary are consistent with the methods run and all analytes are included?
- Data transcribed correctly and calculations verified*? JSD 2/15/24

Comments: _____

ADMINISTRATIVE REVIEWER: _____ DATE: _____

- Documentation of the container, including the kit lot number and expiration date, is included in FA?
- Agency Case #, Lab #, and evidence description match submission form?
- Submitting agency, investigator, suspect, and CC all match submission form?
- Chain of Custody complete and dated appropriately?
- Are all pages numbered and initialed on the examination documents?
- Case number (agency or lab number) written on all pages of the case file?
- Is the exam end date documented in the case file consistent with the end date in LIMS?
- Appropriate review(s) have been completed?

Comments: _____

NIA JSD 2/15/24

DIRECTOR REVIEWER: _____ DATE: _____

- Do the report and associated paperwork meet administrative expectations?
- Have the appropriate reviews been completed?

Comments: _____

Check Mark, / or X = pass, NA = Not Applicable

*If calculations are completed using controlled, secured, & approved software the calculations do not need to be verified.

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Result Report Laboratory Case Number: **FN12272201**
 Item Number: **010**

Lot #:

	Channel A	Channel B
Replicate 1	0.0103	0.0102
Replicate 2	0.0100	0.0102

Additional replicates: No

Mean	0.0102
-5%	0.0097
+5%	0.0107
%CV	1.23%

Expanded Uncertainty	4.3%
Uncertainty Interval	0.001

Blood Analysis Result (99.73% Confidence Interval)

0.010 ± 0.001 g/100 ml ethanol

Ethanol-010 Certified Concentration 10.00 ± 0.05 mg/dL

$$\% \text{ recovery} = \frac{\text{mean}}{\text{true value}} \times 100$$

$$\% \text{ rec.} = \frac{0.0102}{0.0100} \times 100$$

$$\% \text{ rec.} = 102\%$$

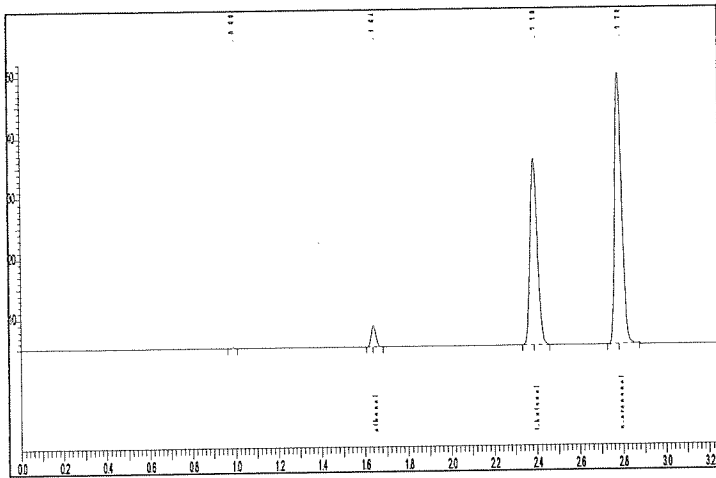
See 02122024 BAC for supporting documents.

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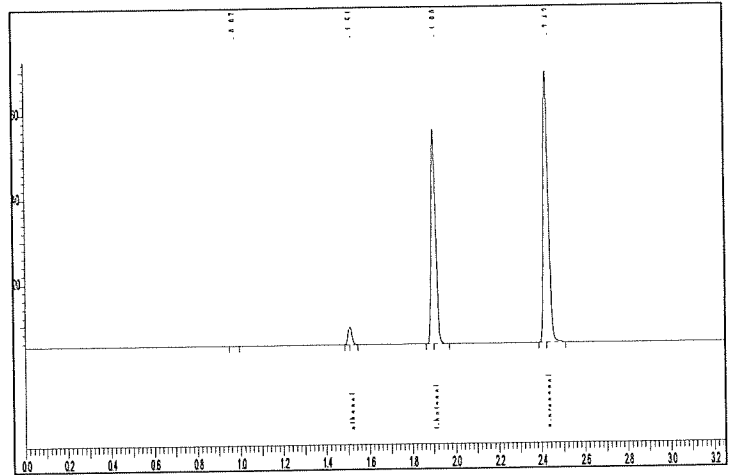
Sequence : C:\TC Data\Data\02122024\ALC 02122024.idx
 Sample Name : FN12272201 010
 Data Acquisition : Feb 12, 2024 at 03:31:45 PM
 Cycle : 23
 Instrument Name : Clarus 580 GC
 Report Date : Feb 13, 2024 at 08:06:46 AM
 Sequence Name: : 02122024
 Inst Method : c:\tc data\methods\alc gc method.mth
 Report : C:\TC Data\Methods\ALCreport.tpm

Channel A:
 Result File : C:\TC Data\Data\02122024\02122024_A023-20240213-080539.rst
 Proc Method : c:\tc data\data\02122024\alc a cal 02122024.mth
 Cal Method : c:\tc data\data\02122024\alc a cal 02122024.mth

Channel B:
 Result File : C:\TC Data\Data\02122024\02122024_B023-20240213-080539.rst
 Proc Method : c:\tc data\data\02122024\alc b cal 02122024.mth
 Cal Method : c:\tc data\data\02122024\alc b cal 02122024.mth



Channel A Chromatogram



Channel B Chromatogram

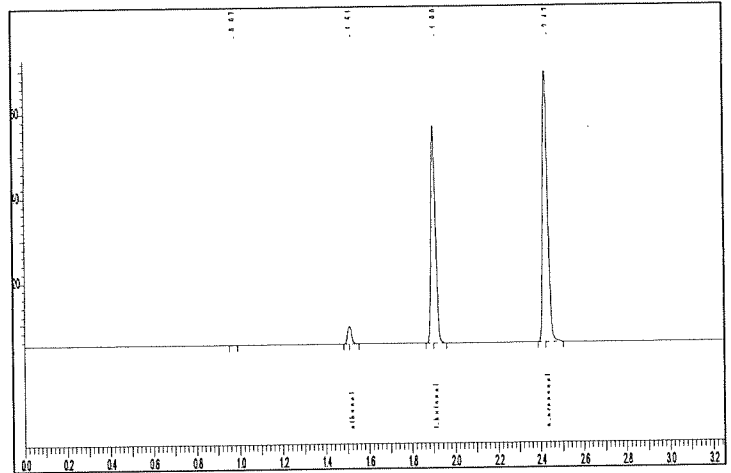
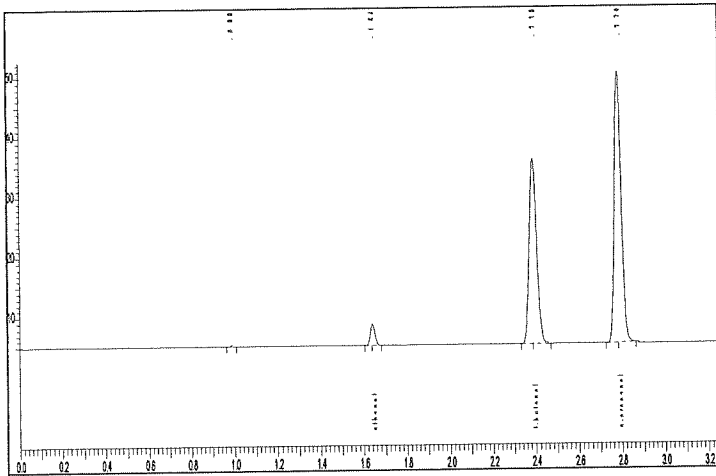
Peak #	Ret (min)	Compound	Area	Amount (g/100 ml)
2	1.640	ethanol	5562	0.0103
3	2.388	t-butanol	73696	0.9974
4	2.783	n-propanol	100245	1.0000

Peak #	Ret (min)	Compound	Area	Amount (g/100 ml)
2	1.509	ethanol	5395	0.0102
3	1.903	t-butanol	74963	0.9989
4	2.425	n-propanol	102175	1.0000

Sequence : C:\TC Data\Data\02122024\ALC 02122024.idx
 Sample Name : FN12272201 010 Instrument Name : Clarus 580 GC
 Data Acquisition : Feb 12, 2024 at 03:41:45 PM Report Date : Feb 13, 2024 at 08:06:46 AM
 Cycle : 24 Sequence Name: : 02122024
 Inst Method : c:\tc data\methods\alc gc method.mth
 Report : C:\TC Data\Methods\ALCreport.tpm

Channel A:
 Result File : C:\TC Data\Data\02122024\02122024_A024-20240213-080539.rst
 Proc Method : c:\tc data\data\02122024\alc a cal 02122024.mth
 Cal Method : c:\tc data\data\02122024\alc a cal 02122024.mth

Channel B:
 Result File : C:\TC Data\Data\02122024\02122024_B024-20240213-080539.rst
 Proc Method : c:\tc data\data\02122024\alc b cal 02122024.mth
 Cal Method : c:\tc data\data\02122024\alc b cal 02122024.mth



Peak #	Ret (min)	Compound	Area	Amount (g/100 ml)
2	1.640	ethanol	5476	0.0100
3	2.388	t-butanol	74274	0.9950
4	2.784	n-propanol	101280	1.0000

Peak #	Ret (min)	Compound	Area	Amount (g/100 ml)
2	1.509	ethanol	5479	0.0102
3	1.902	t-butanol	75213	0.9933
4	2.425	n-propanol	103087	1.0000

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-10

Ethyl alcohol

Catalog Number: E-040
Solution Lot: FN12272201
Expiration: February 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%	10.00 ± 0.05 mg/dL
<ul style="list-style-type: none"> ◆ 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.




 Darron Ellsworth, Quality Assurance Manager

May 11, 2023

Date

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 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	FN12272201	9.92	0.8
Previous Lot	FN04282009	10.08	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%
Residual Water Analysis by Karl Fischer Coulometry	20384212 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	Standard Solution
<p>Analysis Method: GC/FID</p> <p>Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness</p> <p>Temp Program: 35°C hold 5 min to 260°C at 20°C/min hold 2 min</p> <p>Injector Temp: Cool-on-Column</p> <p>Detector Temp: 325°C</p>	<p>Analysis Method: GC/FID Headspace</p> <p>Column: DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness</p> <p>Temp Program: 40°C hold 12 min</p> <p>Injector Temp: 200°C</p> <p>Detector Temp: 250°C</p>
<p>Chromatogram for Neat Material (FD1A, (8-002-13-PER-11055 PR11182101 E.D)) showing a major peak at 1.463 min and several smaller peaks at 1.049, 2.245, 6.585, 7.051, 8.246, 9.233, 11.209, 12.011, 13.442, 14.251, and 14.951 min.</p>	<p>Chromatogram for Standard Solution (FD1A, Peak Signal (F-010-20-FN127201 E.D)) showing a single sharp peak at 6.585 min labeled 'Ethanol'.</p>

COA Revision History

Revision No.	Date	Reason for Revision
00	May 11, 2023	Initial version.

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