Scottsdale Crime Lab

# VENDOR CONTROL INSERTS FOR BLOOD SAMPLES ANALYZED:

## December 7, 2011---April 9, 2012

Please make copies only, do not remove or mix these items with other time periods.

# Certificate of Analysis

## Ethanol 0.400 Calibrator

| | |
|---|---|
| Solution Lot | 091610-4 |
| Preparation Date | 09/16/10 |
| Prepared By | RFB B1463 |
| Method | Gravimetric |
| Solvent | UltraPure Water |
| Amount | 500 ml |
| Storage | Working container: room temp<br>Stock solution: refrigerate |
| Expiration Date | 09/2013 |
| | |
| Analysis Method | GC/FID |
| Calibration Curve | Linear Regression |
| Number of Points | 4 |
| Date Analyzed | 09/30/10 |
| Linearity | 0.9999 |
| Calibrators | Cerilliant[1] |
| Measured Value | 0.399[2] |
| Difference from target | 0.001 |
| | |
| Verified | RFB B1463 |

[1] 0.4, 0.2, 0.1, and 0.02 calibrators, respectively: Cerilliant FN040909-01, Cerilliant FN070209-01, Cerilliant FN 102609-03, and Cerilliant FN 030409-01

[2] Average of 4 measurements

# Certificate of Analysis

## Ethanol 0.200 Calibrator

| | |
|---|---|
| Solution Lot | 091610-2 |
| Preparation Date | 09/16/10 |
| Prepared By | RFB B1463 |
| Method | Gravimetric |
| Solvent | UltraPure Water |
| Amount | 500 ml |
| Storage | Working container: room temp<br>Stock solution: refrigerate |
| Expiration Date | 09/2013 |
| | |
| Analysis Method | GC/FID |
| Calibration Curve | Linear Regression |
| Number of Points | 4 |
| Date Analyzed | 09/30/10 |
| Linearity | 0.9999 |
| Calibrators | Cerilliant[1] |
| Measured Value | 0.199[2] |
| Difference from target | 0.001 |
| | |
| Verified | RFB B1463 |

[1] 0.4, 0.2, 0.1, and 0.02 calibrators, respectively: Cerilliant FN040909-01, Cerilliant FN070209-01, Cerilliant FN 102609-03, and Cerilliant FN 030409-01

[2] Average of 4 measurements

# Certificate of Analysis

## Ethanol 0.100 Calibrator

| | |
|---|---|
| Solution Lot | 091610-1 |
| Preparation Date | 09/16/10 |
| Prepared By | RFB B1463 |
| Method | Gravimetric |
| Solvent | UltraPure Water |
| Amount | 500 ml |
| Storage | Working container: room temp<br>Stock solution: refrigerate |
| Expiration Date | 09/2013 |
| | |
| Analysis Method | GC/FID |
| Calibration Curve | Linear Regression |
| Number of Points | 4 |
| Date Analyzed | 09/30/10 |
| Linearity | 0.9999 |
| Calibrators | Cerilliant[1] |
| Measured Value | 0.099[2] |
| Difference from target | 0.001 |
| | |
| Verified | RFB B1463 |

[1] 0.4, 0.2, 0.1, and 0.02 calibrators, respectively: Cerilliant FN040909-01, Cerilliant FN070209-01, Cerilliant FN 102609-03, and Cerilliant FN 030409-01

[2] Average of 4 measurements

# Certificate of Analysis

## Ethanol 0.020 Calibrator

| | |
|---|---|
| Solution Lot | 091610-02 |
| Preparation Date | 09/16/10 |
| Prepared By | RFB B1463 |
| Method | Gravimetric |
| Solvent | UltraPure Water |
| Amount | 500 ml |
| Storage | Working container: room temp<br>Stock solution: refrigerate |
| Expiration Date | 09/2013 |
| | |
| Analysis Method | GC/FID |
| Calibration Curve | Linear Regression |
| Number of Points | 4 |
| Date Analyzed | 09/30/10 |
| Linearity | 0.9999 |
| Calibrators | Cerilliant[1] |
| Measured Value | 0.021[2] |
| Difference from target | 0.001 |
| | |
| Verified | RFB B1463 |

[1] 0.4, 0.2, 0.1, and 0.02 calibrators, respectively: Cerilliant FN040909-01, Cerilliant FN070209-01, Cerilliant FN 102609-03, and Cerilliant FN 030409-01

[2] Average of 4 measurements

# Whole Blood Ethanol Control Level 2

CE

## INTENDED USE

**FOR IN VITRO DIAGNOSTIC USE**

**LiquiSP$_x$**™ Whole Blood Ethanol Control is an assayed quality control material intended for use in monitoring the accuracy and precision of the quantitative determination of ethanol in whole blood.

## SUMMARY AND PRINCIPLE

This product is to be used exactly as directed for the patient sample in order to monitor, and thus minimize the potential for technical and performance errors in routine testing.

## PRODUCT DESCRIPTION

**LiquiSP$_x$** Whole Blood Ethanol Control is prepared from stabilized normal human whole blood with the addition of ethanol. This product has been assigned lot-specific ethanol values using quantitative analytical methods. This product is packaged 5.0 mL per vial.

## STORAGE AND STABILITY

**LiquiSP$_x$** Whole Blood Ethanol Control is stable until the expiration date on the package when stored unopened at ≤ -20° C and 30 days after opening when stored at 2-8° C. Once thawed and unopened, the product is stable for 12 months at 2-8°C. This product may be thawed and re-frozen one time only. Discard any contaminated material. Microbial contamination is evidenced by an increase in turbidity and/or a characteristic odor.

## PRECAUTIONS

**Human source material. Treat as potentially infectious.**

Each serum/plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

This product contains 0.09% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive compounds. Flush with excess water upon disposal.

## PROCEDURE

Allow the refrigerated controls to warm to room temperature (18-25° C) and gently swirl the control material prior to use in order to ensure product homogeneity. QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

## LIMITATIONS

This material is a control for methods listed in the ASSIGNED VALUES section; it is not to be used as a calibrator. Accurate and reproducible results are dependent upon properly functioning instruments, reagents, standardization, and proper laboratory techniques. Individual laboratories may not obtain the mean assigned value as listed.

## VALUE ASSIGNMENT

The mean values and expected ranges printed in this insert were derived from extensive replicate analyses and are specific for this lot.

Values listed below were generated by Cliniqa, the reagent/instrument manufacturer and/or independent laboratories in accordance with an established protocol.

Procedural or assay modifications may alter the mean value obtained. Each laboratory should establish its own parameters of precision; use the mean assigned values and expected ranges provided only as guidelines.

## ASSIGNED VALUES

| Level 2 | | Lot No.: 1002171<br>Exp. Date: 2014-03 | |
|---|---|---|---|
| **Method** | **Units** | **Mean** | **Expected Range** |
| **Gas Chromatography** | mg/dL | 194 | 175 - 214 |

## REFERENCES

Baselt, R.C. Analytical Procedures for Therapeutic Drug Monitoring and Emergency Toxicology. Littleton, MA, PSG Publishing, 1987.

IVD **For in vitro diagnostic use**

**See package insert for proper use**

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## RE-ORDER INFORMATION
## Whole Blood Ethanol Control

| Catalog No. | Catalog No. | Catalog No. |
|---|---|---|
| REF 93211 | REF 93212 | REF 93213 |
| Level 1, 6 x 5 mL | Level 2, 6 x 5 mL | Level 3, 6 x 5 mL |

CLINIQA®

33101_03 3/25/10

# Whole Blood Ethanol Control Level 2

LiquiSP$_x$™

CE

## INTENDED USE

**FOR IN VITRO DIAGNOSTIC USE**

**LiquiSP$_x$**™ Whole Blood Ethanol Control is an assayed quality control material intended for use in monitoring the accuracy and precision of the quantitative determination of ethanol in whole blood.

## SUMMARY AND PRINCIPLE

This product is to be used exactly as directed for the patient sample in order to monitor, and thus minimize the potential for technical and performance errors in routine testing.

## PRODUCT DESCRIPTION

**LiquiSP$_x$** Whole Blood Ethanol Control is prepared from stabilized normal human whole blood with the addition of ethanol. This product has been assigned lot-specific ethanol values using quantitative analytical methods. This product is packaged 5.0 mL per vial.

2°c – 8°c

## STORAGE AND STABILITY

**LiquiSP$_x$** Whole Blood Ethanol Control is stable until the expiration date on the package when stored unopened at 2-8° C and 45 days after opening when stored at 2-8° C. Discard any contaminated material. Microbial contamination is evidenced by an increase in turbidity and/or a characteristic odor.

## ⚠ PRECAUTIONS

**Human source material. Treat as potentially infectious.**

Each serum/plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

This product contains 0.09% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive compounds. Flush with excess water upon disposal.

## PROCEDURE

Allow the refrigerated controls to warm to room temperature (18-25° C) and gently swirl the control material prior to use in order to ensure product homogeneity. QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

## LIMITATIONS

This material is a control for methods listed in the ASSIGNED VALUES section; it is not to be used as a calibrator. Accurate and reproducible results are dependent upon properly functioning instruments, reagents, standardization, and proper laboratory techniques. Individual laboratories may not obtain the mean assigned value as listed.

## VALUE ASSIGNMENT

The mean values and expected ranges printed in this insert were derived from extensive replicate analyses and are specific for this lot.

Values listed below were generated by Cliniqa, the reagent/instrument manufacturer and/or independent laboratories in accordance with an established protocol.

Procedural or assay modifications may alter the mean value obtained. Each laboratory should establish its own parameters of precision; use the mean assigned values and expected ranges provided only as guidelines.

## ASSIGNED VALUES

| Level 2 | | Lot No.: 1002171A Exp. Date: 2014-03 | |
|---|---|---|---|
| **Method** | **Units** | **Mean** | **Expected Range** |
| Gas Chromatography | mg/dL | 194 | 175 - 214 |

## REFERENCES

Baselt, R.C. Analytical Procedures for Therapeutic Drug Monitoring and Emergency Toxicology. Littleton, MA, PSG Publishing, 1987.

IVD **For in vitro diagnostic use**

**See package insert for proper use**

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## RE-ORDER INFORMATION
## Whole Blood Ethanol Control

| Catalog No. | Catalog No. | Catalog No. |
|---|---|---|
| REF 93211 | REF 93212 | REF 93213 |
| Level 1, 6 x 5 mL | Level 2, 6 x 5 mL | Level 3, 6 x 5 mL |

CLINIQA®

33101_04 12/6/10

Cerilliant®

# *Certificate of Analysis*

## *Certified Reference Standard - NIST Traceable*

## Ethanol-10

*Ethyl Alcohol*

ISO GUIDE 34
ACCREDITED
CERTIFICATE AR1353

ISO/IEC 17025
ACCREDITED
CERTIFICATE AT1352

ISO 9001:2000
CERTIFIED
CERTIFICATE 3854

| | |
|---|---|
| **Catalog Number:** | E-040 |
| **Solution Lot:** | FN061108-01 |
| **Expiration Date:** | June 2013 |
| **Diluent:** | Water |
| **Volume per Ampule:** | 1.2 mL |
| **Storage:** | Protect from light, refrigerate. Do not freeze. |
| **Intended Use:** | For laboratory use only. Not suitable for human or animal consumption. |

- Expiration Date has been established through real time stability studies
- Ampules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution when dilution or exact volume is required.

| Component | Chromatographic Purity | Concentration |
|---|---|---|
| Ethanol | 100% | 10.00 ± 0.04 mg/dL |

- Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO 17025 and ISO Guide 34 at the 95% confidence interval using a coverage factor of k=2, has been calculated by statistical analysis of our production system and incorporates uncertainty of the purity factor, material density and mass.

### *NIST Traceability:*

- This calibration was conducted using standards whose values are traceable to the SI through NIST.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo using NIST traceable weights. Calibration verification is performed weekly and prior to each use utilizing NIST traceable weights. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is verified against a 4-point calibration curve prepared from a NIST SRM.

### *Solution Standard Analysis and Homogeneity:*

| Solution Standard | Lot Number | Concentration compared Calibration Curve (mg/mL) NIST SRM Lot # 2897 | | Homogeneity %RSD | |
|---|---|---|---|---|---|
| | | Actual Results | Acceptance Criteria | Actual Results | Acceptance Criteria |
| New Lot | FN061108-01 | 10.15 | ± 2.0% | 0.7% | ≤ 2.0% |
| Prior Lot | FN011107-01 | 10.15 | ± 2.0% | 0.3% | ≤ 2.0% |

- Concentration is calculated as the average of multiple analyses compared to a calibration curve prepared from a NIST SRM.
- Homogeneity of the New Lot is ensured through rigorous production process controls developed through statistical analysis and risk assessment of each process and verified by analysis of the solution standard. The %RSD of samples pulled from across the lot demonstrates homogeneity of the New Lot.
- The %RSD of the Prior Lot represents variability of the analysis.

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.

ACLASS® ISO/IEC 17025 Accredited for Testing

Lara Sparks

Lara Sparks, Quality Assurance Director

*February 14, 2009*
Date

## *Solution Standard Assay Parameters*

| | |
|---|---|
| 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 for 12 min |
| Injector Temp: | 200°C |
| Detector Temp: | 250°C |

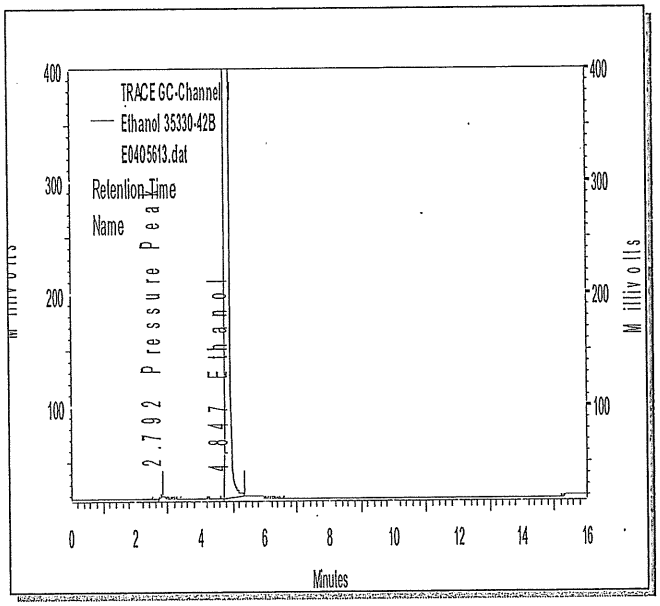
## *NIST Calibration Curve*

| | |
|---|---|
| NIST SRM Lot # | 2897 |
| Calibration Curve: | Linear Regression |
| Number of Points | 4 |
| Linearity (r): | 1.000 |

*Each point is analyzed in triplicate*

## *Neat Material Verification*

GC/FID Headspace Analysis




*COA Revision History*

| Revision | Date | Reason for Revision |
|---|---|---|
| 00 | 8/4/2008 | Initial version |
| 01 | 2/18/2009 | Revised COA template to comply with ISO/IEC 17025 requirements. |
| | | |

Cerilliant®

# Certificate of Analysis

## Certified Reference Material - NIST Traceable

## Ethanol-20

*Ethyl Alcohol*

ISO GUIDE 34 ACCREDITED CERTIFICATE AR1351
ISO/IEC 17025 ACCREDITED CERTIFICATE AT1352
ISO 9001:2000 CERTIFIED CERTIFICATE 3654

| | |
|---|---|
| **Catalog Number:** | E-056 |
| **Solution Lot:** | FN030409-01 |
| **Expiration Date:** | March 2014 |
| **Diluent:** | Water |
| **Volume per Ampule:** | 1.2 mL |
| **Storage:** | Protect from light, refrigerate. Do not freeze. |
| **Intended Use:** | For laboratory use only. Not suitable for human or animal consumption. |

- Expiration Date has been established through real time stability studies.
- Ampules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this solution standard before diluting to the desired concentration.

| Component | Chromatographic Purity | Concentration |
|---|---|---|
| Ethanol | 100% | 20.00 ± 0.07 mg/dL |

- Chromatographic purity of the solution is verified post ampuling to provide assurance of no contamination or degradation during manufacturing.
- Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO/IEC 17025 and ISO Guide 34 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production system. Uncertainty includes uncertainty of the purity factor, material density and mass. Purity factor uncertainty incorporates uncertainty of all analyses performed to characterize the raw material including chromatographic purity and residual water. Mass uncertainty incorporates uncertainty of the balance in its installed environment and weighing technique and was determined through repeatability experiments using Cerilliant established weighing procedures.
- This standard meets the definition of a Certified Reference Material in accordance with ISO Guide 34.

### Traceability

- This standard and its preparation are fully traceable to the SI through NIST.
- This standard was gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo, an ISO/IEC 17025 accredited company, using NIST traceable weights. Calibration verification is performed weekly through the range of the balance and then prior to each use. All calibration verifications are performed utilizing NIST traceable weights which are externally calibrated on an annual basis by a qualified ISO 17025 accredited calibration laboratory. Weigh tapes verifying pre-use balance calibration are included in the production batch record for this standard. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is analytically verified by multiple analyses directly to a NIST SRM.

*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 when stored unopened as recommended. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.*

Lara Sparks

Lara Sparks, Quality Assurance Director

*April 27, 2009*
Date

## Analytical Verification of Solution Standard Concentration and Homogeneity

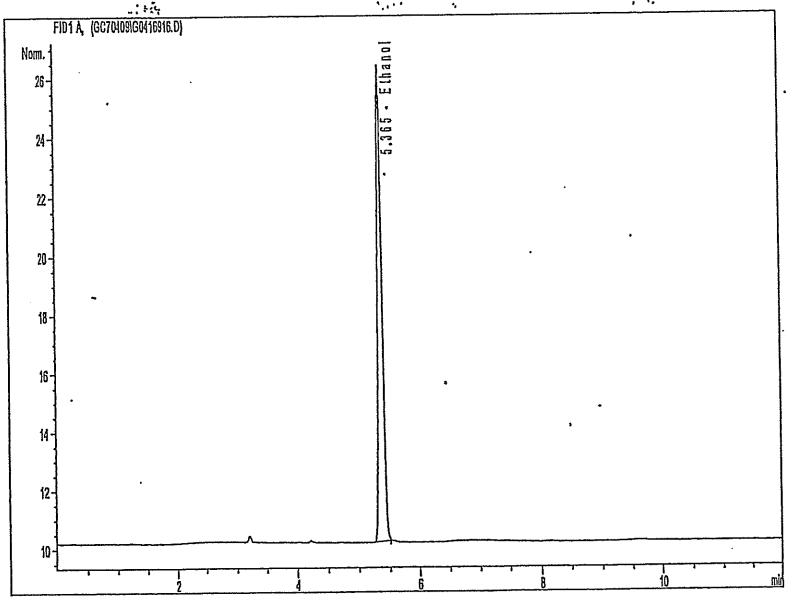
| Solution Standard | Lot Number | Concentration (mg/mL) | NIST SRM Lot and Concentration used for Assay | %RSD | |
|---|---|---|---|---|---|
| New Lot | FN030409-01 | 20.41 | SRM 2891 | 1.1% | Homogeneity |
| Prior Lot | FN022207-02 | 20.02 | 0.01951% ± 0.00018% | 2.3% | System Suitability |

- Concentration is calculated as the average of multiple analyses by GC Headspace compared directly to the NIST SRM lot listed above. Acceptance criteria of ±2.0% incorporates variability of the analysis. Concentration of the NIST SRM lot is as certified by NIST.
- Homogeneity of the New Lot is ensured through the use of validated processes and verified by analysis. The %RSD of samples pulled from across the lot demonstrates homogeneity of the New Lot.
- The %RSD of the Prior Lot represents variability of the analysis performed during solution standard release testing and system suitability. Triplicate injections of the Prior Lot are bracketed at the beginning and end of the sequence. %RSD criteria of ≤2% ensures system performance throughout the sequence.
- All testing equipment is fully qualified through an installation qualification and annual operational qualifications.

## Solution Standard Assay Parameters

| | |
|---|---|
| **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 for 12 min |
| **Injector Temp:** | 200°C |
| **Detector Temp:** | 250°C |

## Raw Material Verification by GC/FID



Cerilliant®
Analytical Reference Standards

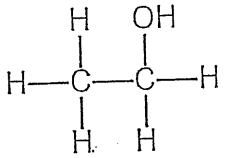
E-045
FN080307-02
Revision 2

ISO GUIDE 34
ACCREDITED
CERTIFICATE AR1235
ISO/IEC 17025
ACCREDITED
CERTIFICATE AT-1287
ISO 9001:2000
CERTIFIED
CERTIFICATE 3626.

# Certificate of Analysis

## Ethanol-40

*Ethyl alcohol*



| | |
|---|---|
| Catalog Number: | E-045 |
| Solution Lot: | FN080307-02 |
| Expiration Date: | August 2012 |
| Diluent: | Water |
| Volume per Ampule: | 1.2 mL |
| Storage: | Protect from light, refrigerate. Do not freeze. |
| Intended Use: | For laboratory use only. Not suitable for human or animal consumption. |

- Expiration Date has been established through real time stability studies.
- Ampules are overfilled to ensure a minimum 5 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration.

| Component | Chromatographic Purity | Concentration |
|---|---|---|
| Ethanol | 100% | 40.00 ± 1.24 mg/dL |

- Chromatographic purity of the solution is verified post ampuling to provide assurance of no contamination or degradatioin during manufacturing.
- The range of concentration is determined by statistical process control of our production and analysis systems with a 95% confidence.

### Traceability

- The standard and its preparation are fully traceable to the SI through NIST.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo, an ISO/IEC 17025 accredited company, using NIST traceable weights. Calibration verification performed weekly through the range of the balance and then prior to each use. All calibration verifications are performed utilizing NIST traceable weights which are externally calibrated on an annual basis by a qualified ISO 17025 accredited calibration laboratory. Weigh tapes verifying pre-use balance calibration are included in the production batch record for this standard. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is analytically verified by multiple analyses to a calibration curve prepared from a NIST SRM.

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/retest date.

Authorized Signature: Lara Sparks

Lara Sparks, Quality Assurance Director

*April 22, 2009*

Date

Cerilliant Corporation 811 Paloma Drive, Suite A, Round Rock, TX 78665 800-848-7837 / 512-238-9974

## Analytical Verification of Solution Standard Concentration and Homogeneity

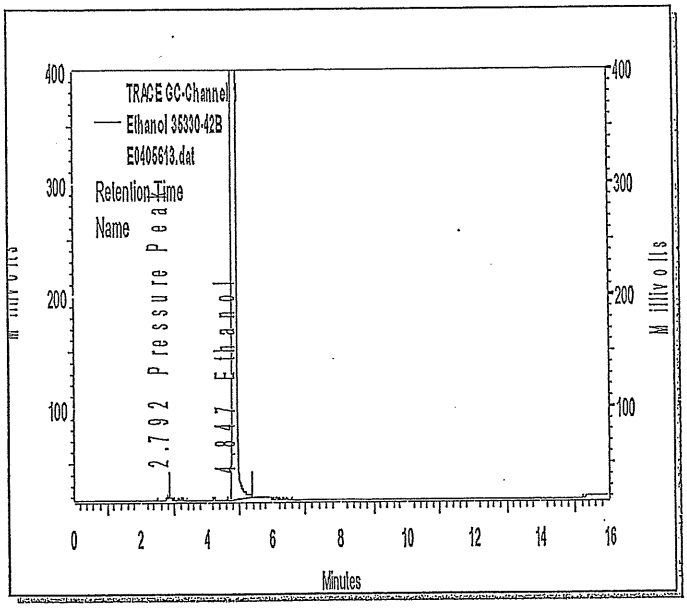
| Solution Standard | Lot Number | Concentration (mg/dL) | % Difference from Target | Homogeneity % RSD |
|---|---|---|---|---|
| New Lot | FN080307-02 | 40.2 | 0.5 | 0.4 |
| Previous Lot | FN082406-01 | 40.5 | 1.2 | 1.3 |

- Concentration values are determined by comparison to an independent calibration curve prepared from a NIST ehtanol standard (SRM 1828a). The concentration range is calculated from the distribution of multiple analyses of the new standard with a 95% degree of confidence.
- Homogeneity of the New Lot 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 demonstrate homogeneity of the New Lot.
- The % RSD of the Previous Lot represents variability of the analysis performed during solution standard release testing. % RSD criteria of < 2% ensures system performance throughout the sequence.
- All testing equipment is fully qualified through an installation qualification and annual operational qualifications. Prior to analysis, system suitability is demonstrated.

## Solution Standard Assay Parameters

| | |
|---|---|
| Analysis Method: | GC/FID Headspace |
| Column: | DB-ALC 30 m x 0.53 mm ID, 3.0 µm film thickness |
| Temp Program: | 40°C Isothermal for 12 minutes |
| Injector Temp: | 200°C |
| Detector Temp: | 250°C |

## Raw Material Verification by GC/FID



Cerilliant®

# *Certificate of Analysis*

## *Certified Reference Standard - NIST Traceable*

## Ethanol-80

*Ethyl Alcohol*

ISO GUIDE 34 ACCREDITED CERTIFICATE AR1324
ISO/IEC 17025 ACCREDITED CERTIFICATE AT1324
ISO 9001:2000 CERTIFIED CERTIFICATE 3854

| | |
|---|---|
| **Catalog Number:** | E-030 |
| **Solution Lot:** | FN042808-02 |
| **Expiration Date:** | April 2013 |
| **Diluent:** | Water |
| **Volume per Ampule:** | 1.2 mL |
| **Storage:** | Protect from light, refrigerate. Do not freeze. |
| **Intended Use:** | For laboratory use only. Not suitable for human or animal consumption. |

- Expiration Date has been established through real time stability studies.
- Ampules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution when dilution or exact volume is required.

| Component | Chromatographic Purity | Concentration |
|---|---|---|
| Ethanol | 100% | 80.0 ± 0.2 mg/dL |

- Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO 17025 and ISO Guide 34 at the 95% confidence interval using a coverage factor of k=2, has been calculated by statistical analysis of our production system and incorporates uncertainty of the purity factor, material density and mass.

### *NIST Traceability:*

- This calibration was conducted using standards whose values are traceable to the SI through NIST.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo using NIST traceable weights. Calibration verification is performed weekly and prior to each use utilizing NIST traceable weights. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is verified against a 4-point NIST SRM calibration curve.
- A second NIST SRM control is used to ensure accuracy during solution standard analysis.

### *Solution Standard Analysis and Homogeneity:*

| Solution Standard | Lot Number | Concentration compared Calibration Curve (mg/mL) NIST SRM Lot #2897 | | Homogeneity %RSD | |
|---|---|---|---|---|---|
| | | Actual Results | Acceptance Criteria | Actual Results | Acceptance Criteria |
| New Lot | FN042808-02 | 81.6 | ±2.0% | 0.0% | ≤2.0% |
| Prior Lot | FN111406-01 | 80.6 | ±2.0% | 1.7% | ≤2.0% |
| NIST Control | NIST 2893 | 81.6 | ±2.0% | 1.1% | ≤2.0% |

- Concentration is calculated as the average of multiple analyses compared to a NIST SRM calibration curve.
- Homogeneity of the New Lot is ensured through rigorous production process controls developed through statistical analysis and risk assessment of each process and verified by analysis of the solution standard. The %RSD of samples pulled from across the lot demonstrates homogeneity of the New Lot.
- The %RSD of the Prior Lot represents variability of the analysis.

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.

ACLASS® ISO/IEC 17025 Accredited for Testing

Lara Sparks, Quality Assurance Director

*January 26, 2009*
Date

## *Solution Standard Assay Parameters*

| | |
|---|---|
| **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 for 12 min |
| **Injector Temp:** | 200°C |
| **Detector Temp:** | 250°C |

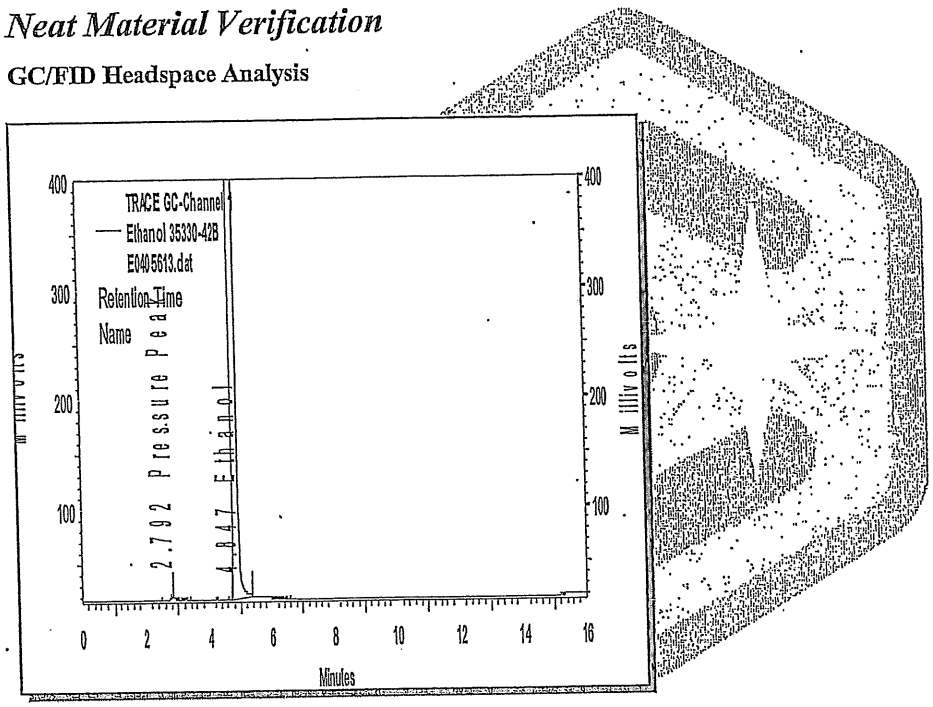
## *NIST Calibration Curve*

| | |
|---|---|
| **NIST SRM Lot #** | 2897 |
| **Calibration Curve:** | Linear Regression |
| **Number of Points** | 4 |
| **Linearity (r):** | 1.000 |

*Each point is analyzed in triplicate*

## *Neat Material Verification*

**GC/FID Headspace Analysis**




## *COA Revision History*

| Revision | Date | Reason for Revision |
|---|---|---|
| 00 | 6/11/2008 | Initial version |
| 01 | 8/19/2008 | Revised Footnote 2 to state "analytical concentration" from "prepared concentration". |
| 02 | 1/26/2009 | Revised COA template to comply with ISO/IEC 17025 requirements. |
| | | |

Cerilliant®



# *Certificate of Analysis*

## *Certified Reference Standard - NIST Traceable*

## Ethanol-100

*Ethyl Alcohol*

ISO GUIDE 34
CERTIFICATE AR1353

ISO/IEC 17025
CERTIFICATE AT1352

ISO 9001:2000
CERTIFICATE 3654

| | |
|---|---|
| Catalog Number: | E-031 |
| Solution Lot: | FN102609-03 |
| Expiration Date: | October 2014 |
| Diluent: | Water |
| Volume per Ampoule: | 1.2 mL |
| Storage: | Refrigerate. Do not freeze. |
| Intended Use: | For laboratory use 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.

| Component | Solution Chromatographic Purity | Certified Concentration |
|---|---|---|
| Ethanol | 100% | 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 Guide 34 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 0.175% and the relative expanded uncertainty is 0.35% 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 172025 standards – See page 2.
- Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred.

### *Traceability to SI through NIST:*

- This standard has been prepared and certified under the ISO Guide 34 and ISO/IEC 17025 standards and meets the requirements of a Certified Reference Material as defined by ISO.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo to ISO 17025 requirements and using NIST traceable weights. Qualification of each balance includes the assignment of a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure each weighing complies with USP tolerances of NMT 0.1% relative uncertainty.
- Balance calibration adjustments are performed weekly utilizing the balance's internal adjustment mechanism and with NIST traceable weights.
- Balance calibration is verified prior to each use and is performed utilizing NIST traceable weights. Weigh tapes from the balance calibration are included in the production batch record for this standard. Production data package available upon request.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Weight sets used for all balance calibrations are calibrated externally by an ISO 17025 accredited calibration laboratory to NIST standards.
- Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method. See page 2.

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.

Lara Sparks, Quality Assurance Director

*November 5, 2009*
Date

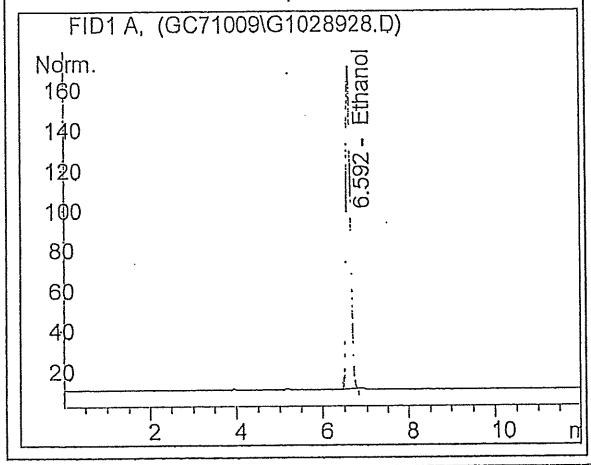
*Analytical Verification of Solution Standard Concentration and Batch Homogeneity:*

| Solution Standard | Lot Number | Results compared to NIST SRM Lot 2894 (mg/dL) | Results compared to Control | Homogeneity (ampoule to ampoule consistency) %RSD |
|---|---|---|---|---|
| New Lot | FN102609-03 | 100.0 | -0.02% | 1.22% |
| Prior Lot | FN091009-01 | 100.0 | -0.03% | 1.14% |
| Acceptance Criteria | | ±2% | ±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 Prior Lot represents system suitability on the date of analysis. Triplicate injections of the Prior 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.

## *Solution Standard Assay Parameters*

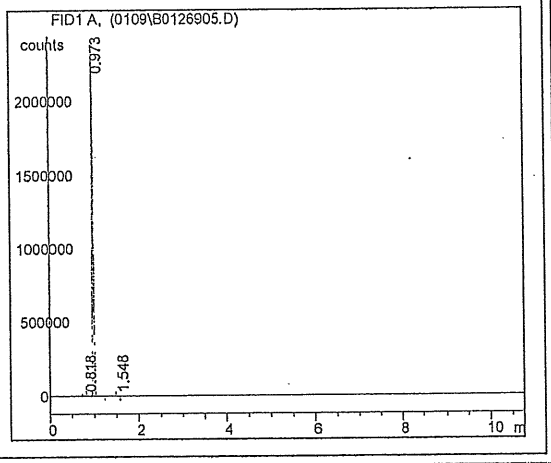
| | |
|---|---|
| Analysis Method: | GC/FID Headspace |
| Column: | DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness |
| Temp Program: | 40°C hold for 12 min |
| Injector Temp: | 200°C |
| Detector Temp: | 250°C |




## *Neat Material Analysis*

| | |
|---|---|
| Purity by GC/FID Analysis: | 100.00% |
| Water Content by Karl Fischer: | 0.08% |
| Purity Factor: | 99.92% |

*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.*



Cerilliant®
Analytical Reference Standards

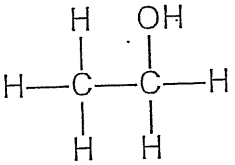
E-041
FN020108-01
Revision 1

ISO GUIDE 34
ACCREDITED
CERTIFICATE AR1353
ISO/IEC 17025
ACCREDITED
CERTIFICATE AT1352
ISO 9001:2000
CERTIFIED
CERTIFICATE 3654

# Certificate of Analysis

## Ethanol-150

*Ethyl alcohol*



| | |
|---|---|
| **Catalog Number:** | E-041 |
| **Solution Lot:** | FN020108-01 |
| **Expiration Date:** | February 2013 |
| **Solvent:** | Water |
| **Amount per Ampule:** | 1.2 mL |
| **Storage:** | Protect from light, refrigerate. Do not freeze. |
| **Handling:** | We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. |
| **Intended Use:** | For laboratory use only. Not suitable for human or animal consumption. |

| Component | Chromatographic Purity[1] | Concentration[2] |
|---|---|---|
| Ethanol | 99% | 150.0 ± 4.7 mg/dL |

1 See following pages for more information.

2 The range of the prepared concentration is determined by statistical process control of our production and analysis systems with a 95% confidence.

Cerilliant certifies that this standard meets or exceeds the specifications stated in this data sheet. Accuracy is ensured by purity determinations and gravimetric preparation using balances calibrated with NIST traceable weights. Precision is guaranteed by triplicate analysis and comparison to previous lots (when available). Homogeneity is demonstrated by random analysis of the ampuled standard.

Authorized Signature: Lara Sparks

Lara Sparks, Quality Assurance Director

*January 23, 2009*

Date

Cerilliant Corporation 811 Paloma Drive, Suite A, Round Rock, TX 78665 800-848-7837 / 512-238-9974

## *Standard Solution Comparability*

| *Standard Solution* | *Lot Number* | *Concentration* [3] *(mg/dL)* | *% Difference from Target* |
|---|---|---|---|
| New Lot | FN020108-01 | 152.8 | 1.9 |
| Previous Lot | FN101206-01 | 153.3 | 2.2 |

## *Standard Solution Homogeneity*

| *Ampuling Position* | *Concentration* [3] *(mg/dL)* | *Mean* | *% RSD* |
|---|---|---|---|
| Early | 152.8 | | |
| Middle | 152.9 | | |
| Late | 152.8 | 152.8 | 0.0 |

[3] Concentration values are determined by comparison to an independent calibration curve prepared from a NIST standard (SRM 2897). We suggest using the prepared concentration value for dilutions. The concentration range is calculated from the distribution of multiple analyses of the new standard with a 95% degree of confidence.

## *Standard Solution Assay Parameters*

| | |
|---|---|
| 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 for 12 min |
| Injector Temp: | 200°C |
| Detector Temp: | 250°C |

| | |
|---|---|
| Calibration Curve: | Linear Regression |
| Number of Points: | 4 |
| Linearity (r): | 0.999 |

*Each point is analyzed in triplicate.*

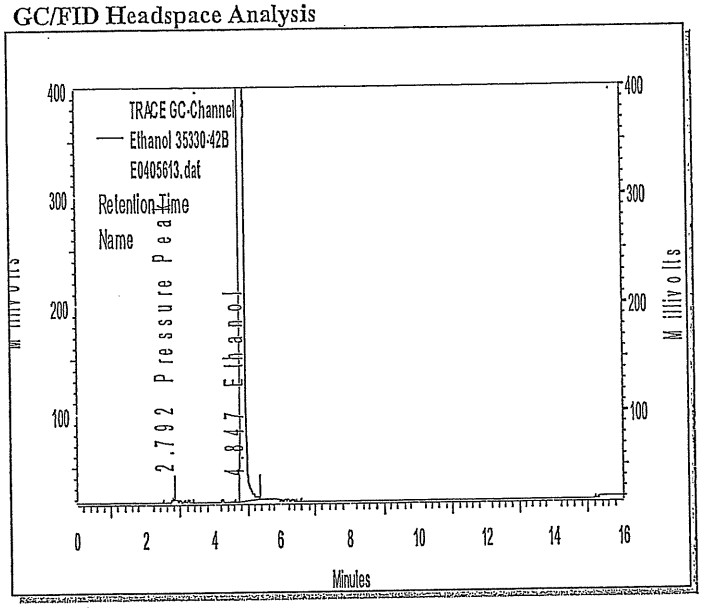
## *Neat Material Data*

| | |
|---|---|
| Compound Name: | Ethanol |
| Compound Lot: | 35330-42B |
| Chromatographic Purity: | 99% |

| | |
|---|---|
| Chemical Formula: | $C_2H_6O$ |
| CAS Number: | 64-17-5 |
| Molecular Weight: | 46.07 |

## *Neat Material Verification*

### GC/FID Headspace Analysis




| | |
|---|---|
| Column: | DB-ALC1 30 m x 0.53 mm, 3 µm film thickness |
| Temp Program: | 40°C (12 min) to 220°C at 40°C/min (5.5 min) |
| Carrier Gas: | Helium |
| Flow Rate: | 2.0 mL/min |
| Detector Temp: | 250°C |
| Injector: | Headspace Sampler |
| Injector Temp: | 200°C |
| HS Oven Temp: | 200°C |
| Injection Volume: | 1.0 mL |
| Incubation Time: | 10 minutes |
| Data File Name: | C:\ChromQuest30\Projects\Default\Data\E0405613.dat |
| Operator: | CAW |
| Instrument: | GC#4 |
| Method: | AM1087 |
| Sample Name: | 35330-42B |
| Acquired: | April 6, 2006 10:37 AM |

| Peak | Compound | Area | Area % |
|---|---|---|---|
| 1 | Pressure peak | NA | NA |
| 2 | Ethanol | 322644078 | 100.0 |
| Total | | | 100.0 |

Cerilliant®

ISO GUIDE 34
CERTIFICATE AR1353

ISO/IEC 17025
CERTIFICATE AT1352

ISO 9001:2000
CERTIFICATE 3054

# *Certificate of Analysis*

## *Certified Reference Standard - NIST Traceable*

## Ethanol-200

*Ethyl Alcohol*

| | |
|---|---|
| **Catalog Number:** | E-032 |
| **Solution Lot:** | FN070209-01 |
| **Expiration Date:** | July 2014 |
| **Diluent:** | Water |
| **Volume per Ampoule:** | 1.2 mL |
| **Storage:** | Refrigerate. Do not freeze. |
| **Intended Use:** | For laboratory use 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.

| Component | Solution Chromatographic Purity | Certified Concentration |
|---|---|---|
| Ethanol | 100% | 200.0 ± 0.7 mg/dL |

- Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO Guide 34 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 0.175% and the relative expanded uncertainty is 0.35% 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 172025 standards – See page 2.
- Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred.

### *Traceability to SI through NIST:*

- This standard has been prepared and certified under the ISO Guide 34 and ISO/IEC 17025 standards and meets the requirements of a Certified Reference Material as defined by ISO.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo to ISO 17025 requirements and using NIST traceable weights. Qualification of each balance includes the assignment of a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure each weighing complies with USP tolerances of NMT 0.1% relative uncertainty.
- Balance calibration adjustments are performed weekly utilizing the balance's internal adjustment mechanism and with NIST traceable weights.
- Balance calibration is verified prior to each use and is performed utilizing NIST traceable weights. Weigh tapes from the balance calibration are included in the production batch record for this standard. Production data package available upon request.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Weight sets used for all balance calibrations are calibrated externally by an ISO 17025 accredited calibration laboratory to NIST standards.
- Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method. See page 2.

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.

Lara Sparks

Lara Sparks, Quality Assurance Director

*August 11, 2009*

Date

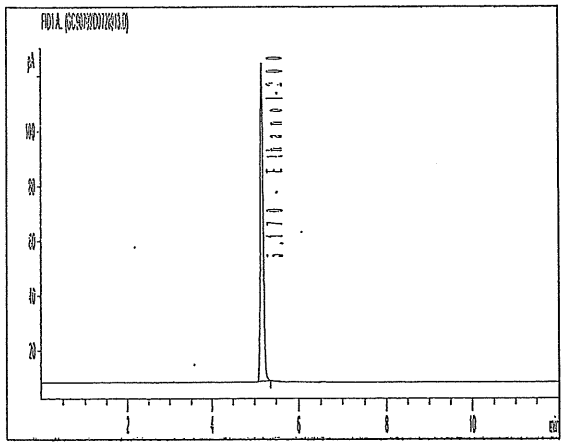
*Analytical Verification of Solution Standard Concentration and Batch Homogeneity:*

| Solution Standard | Lot Number | Results compared to NIST SRM Lot 2895 (mg/dL) | Results compared to Control | Homogeneity (ampoule to ampoule consistency) %RSD |
|---|---|---|---|---|
| New Lot | FN070209-01 | 201.9 | -0.11% | 0.73% |
| Prior Lot | FN110107-02 | 201.3 | -0.39% | 1.53% |
| Acceptance Criteria | | ±2% | ±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 Prior Lot represents system suitability on the date of analysis. Triplicate injections of the Prior 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.

## *Solution Standard Assay Parameters*

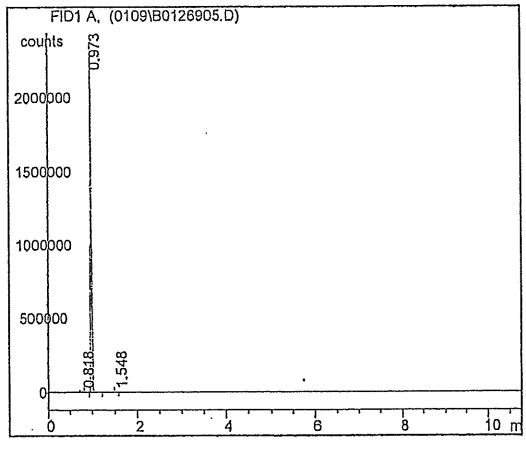
| | |
|---|---|
| Analysis Method: | GC/FID Headspace |
| Column: | DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness |
| Temp Program: | 40°C hold for 12 min |
| Injector Temp: | 200°C |
| Detector Temp: | 250°C |



## *Neat Material Analysis*

| | |
|---|---|
| Purity by GC/FID Analysis: | 100.00% |
| Water Content by Karl Fischer: | 0.08% |
| Purity Factor: | 99.92% |

*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.*



Cerilliant®

ISO GUIDE 34 ACCREDITED CERTIFICATE AR1351
ISO/IEC 17025 ACCREDITED CERTIFICATE AT1352
ISO 9001:2000 CERTIFIED CERTIFICATE 3854

# Certificate of Analysis

## Certified Reference Material - NIST Traceable

## Ethanol-400

*Ethyl Alcohol*

**Catalog Number:** E-036
**Solution Lot:** FN040909-01
**Expiration Date:** April 2014
**Diluent:** Water
**Volume per Ampule:** 1.2 mL
**Storage:** Protect from light, refrigerate. Do not freeze.
**Intended Use:** For laboratory use only. Not suitable for human or animal consumption.

- Expiration Date has been established through real time stability studies.
- Ampules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this solution standard before diluting to the desired concentration.

| Component | Chromatographic Purity | Concentration |
|---|---|---|
| Ethanol | 100% | 400.0 ± 1.4 mg/dL |

- Chromatographic purity of the solution is verified post ampuling to provide assurance of no contamination or degradation during manufacturing.
- Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO/IEC 17025 and ISO Guide 34 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production system. Uncertainty includes uncertainty of the purity factor, material density and mass. Purity factor uncertainty incorporates uncertainty of all analyses performed to characterize the raw material including chromatographic purity and residual water. Mass uncertainty incorporates uncertainty of the balance in its installed environment and weighing technique and was determined through repeatability experiments using Cerilliant established weighing procedures.
- This standard meets the definition of a Certified Reference Material in accordance with ISO Guide 34.

### Traceability

- This standard and its preparation are fully traceable to the SI through NIST.
- This standard was gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo, an ISO/IEC 17025 accredited company, using NIST traceable weights. Calibration verification is performed weekly through the range of the balance and then prior to each use. All calibration verifications are performed utilizing NIST traceable weights which are externally calibrated on an annual basis by a qualified ISO 17025 accredited calibration laboratory. Weigh tapes verifying pre-use balance calibration are included in the production batch record for this standard. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is analytically verified by multiple analyses directly to a NIST SRM.

*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 when stored unopened as recommended. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.*

Lara Sparks, Quality Assurance Director

May 22, 2009
Date

## Analytical Verification of Solution Standard Concentration and Homogeneity

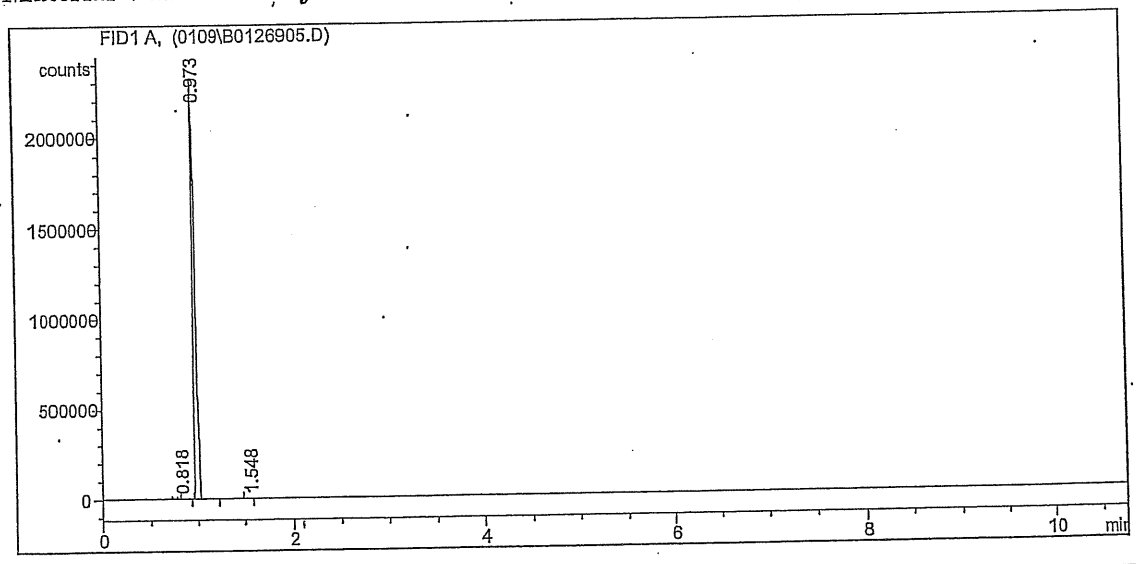
| Solution Standard | Lot Number | Concentration (mg/dL) | NIST SRM Lot and Concentration used for Assay | %RSD | |
|---|---|---|---|---|---|
| New Lot | FN040909-01 | 405.0 | SRM 2896 | 1.7% | Homogeneity |
| Prior Lot | FN092507-01 | 397.7 | 0.2980% ± 0.0030% | 0.9% | System Suitability |

- Concentration is calculated as the average of multiple analyses by GC Headspace compared directly to the NIST SRM lot listed above. Acceptance criteria of ± 2.0% incorporates variability of the analysis. Concentration of the NIST SRM lot is as certified by NIST.
- Homogeneity of the New Lot is ensured through the use of validated processes and verified by analysis. The %RSD of samples pulled from across the lot demonstrates homogeneity of the New Lot.
- The %RSD of the Prior Lot represents variability of the analysis performed during solution standard release testing and system suitability. Triplicate injections of the Prior Lot are bracketed at the beginning and end of the sequence. %RSD criteria of ≤2% ensures system performance throughout the sequence.
- All testing equipment is fully qualified through an installation qualification and annual operational qualifications.

## Solution Standard Assay Parameters

| | |
|---|---|
| **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 for 12 min |
| **Injector Temp:** | 200°C |
| **Detector Temp:** | 250°C |

## Raw Material Verification by GC/FID



Cerilliant®
Analytical Reference Standards

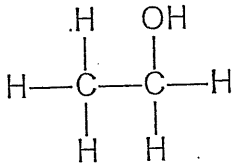
E-053
FN011408-01
Revision 1

ISO GUIDE 34
ACCREDITED
CERTIFICATE AR1353
ISO/IEC 17025
ACCREDITED
CERTIFICATE AT1352
ISO 9001:2000
CERTIFIED
CERTIFICATE 3654

# Certificate of Analysis

## Ethanol-500

*Ethyl alcohol*



| | |
|---|---|
| **Catalog Number:** | E-053 |
| **Solution Lot:** | FN011408-01 |
| **Expiration Date:** | January 2013 |
| **Solvent:** | Water |
| **Amount per Ampule:** | 1.2 mL |
| **Storage:** | Protect from light, refrigerate. Do Not Freeze. |
| **Handling:** | We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. |
| **Intended Use:** | For laboratory use only. Not suitable for human or animal consumption. |

| Component | Chromatographic Purity[1] | Concentration[2] |
|---|---|---|
| Ethanol | 99% | 500.0 ± 15.5 mg/dL |

1 Determined by chromatographic analysis. See following pages for more information.

2 The range of the prepared concentration is determined by statistical process control of our production and analysis systems with a 95% confidence.

Cerilliant certifies that this standard meets or exceeds the specifications stated in this data sheet. Accuracy is ensured by purity determinations and gravimetric preparation using balances calibrated with NIST traceable weights. Precision is guaranteed by triplicate analysis and comparison to previous lots (when available). Homogeneity is demonstrated by random analysis of the ampuled standard.

Authorized Signature: Lara Sparks

Lara Sparks, Quality Assurance Director

*January 23, 2009*

Date

### *Standard Solution Comparability*

| *Standard Solution* | *Lot Number* | *Concentration* [3] *(mg/dL)* | *% Difference from Target* |
|---|---|---|---|
| New Lot | FN011408-01 | 506.7 | 1.3 |
| Previous Lot | FN071406-01 | 505.5 | 1.1 |

### *Standard Solution Homogeneity*

| *Ampuling Position* | *Concentration* [3] *(mg/dL)* | *Mean* | *% RSD* |
|---|---|---|---|
| Early | 505.8 | | |
| Middle | 504.5 | | |
| Late | 509.8 | 506.7 | 0.5 |

[3] Concentration values are determined by comparison to an independent calibration curve prepared from a NIST ethanol standard (SRM 2897). We suggest using the prepared concentration value for dilutions. The concentration range is calculated from the distribution of multiple analyses of the new standard with a 95% degree of confidence.

## *Standard Solution Assay Parameters*

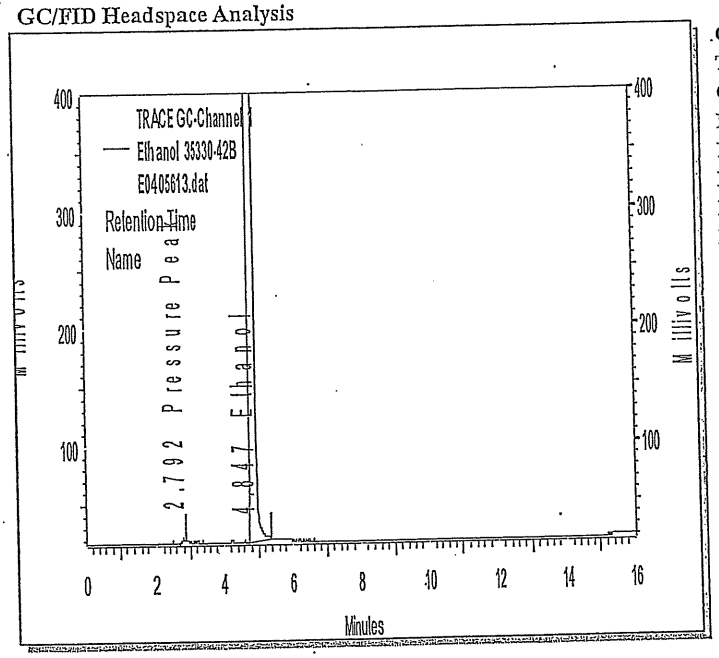
| | | | |
|---|---|---|---|
| Analysis Method: | GC/FID Headspace | Calibration Curve: | Linear Regression |
| Column: | DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness | Number of Points: | 4 |
| Temp Program: | 40°C hold for 12 min | Linearity (r): | 0.999 |
| Injector Temp: | 200°C | | |
| Detector Temp: | 250°C | | |

## *Neat Material Data*

| | | | |
|---|---|---|---|
| Compound Name: | Ethanol | Chemical Formula: | $C_2H_6O$ |
| Compound Lot: | 35330-42B | CAS Number: | 64-17-5 |
| Chemical Purity: | 99% | Molecular Weight: | 46.07 |

### *Spectral and Physical Data*

GC/FID Headspace Analysis




| | |
|---|---|
| Column: | DB-ALC1 30 m x 0.53 mm, 3 µm film thickness |
| Temp Program: | 40°C (12 min) to 220°C at 40°C/min (5.5 min) |
| Carrier Gas: | Helium |
| Flow Rate: | 2.0 mL/min |
| Detector Temp: | 250°C |
| Injector: | Headspace Sampler |
| Injector Temp: | 200°C |
| HS Oven Temp: | 200°C |
| Injection Volume: | 1.0 mL |
| Incubation Time: | 10 minutes |
| Data File Name: | C:\ChromQuest30\Projects\Default\Data\E0405613.dat |
| Operator: | CAW |
| Instrument: | GC#4 |
| Method: | AM1087 |
| Sample Name: | 35330-42B |
| Acquired: | April 6, 2006 10:37 AM |

| Peak | Compound | Area | Area % |
|---|---|---|---|
| 1 | Pressure peak | NA | NA |
| 2 | Ethanol | 322644078 | 100.0 |
| Total | | | 100.0 |