Scottsdale Crime Lab

VENDOR CONTROL INSERTS AND MAINTENANCE LOGS FOR BLOOD SAMPLES ANALYZED:

January 27, 2010 ---- May 1, 2010

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

Police Department
An Internationally Accredited Police Agency Since 1994

Forensic Services Division

7601 B East McKellips Road
Scottsdale, Arizona 85257

PHONE 480-312-5335
FAX 480-312-5222

Memorandum For Record

Date: August 3, 2009

To: Steve Garrett, Forensic Science Division Manager

From: Kris Cano Whitman
Quality Assurance Leader

Re: Authorization of Validation Studies

This memorandum is written to document the authorization of the following instruments validation studies for the Toxicology (Blood Alcohol) discipline. The validation was conducted by P.Allan Kosecki, Criminalist III.

Perkin Elmer Clarus 500 – Serial # 650N9042003
Perkin Elmer Clarus 500 – Serial # 650N9042002

The data for each validation study is contained in the blood alcohol validation notebook. The validation studies consisted of the following:

Linearity
Resolution
Carryover
Accuracy and Precision
Limit of Quanitation
Sensitivity
Concordance

The toxicology section is authorized to conduct blood alcohol analysis using the above listed instruments with an effective date of 8-3-09.

Kris Cano Whitman

Kris Whitman
Quality Assurance Leader

Memorandum for Record

Date: July 28, 2009

To: Kris Cano Whitman, Quality Assurance Leader
Steve Garrett, Forensic Science Division Manager

From: Jennifer S Valdez
Criminalist, Toxicology

Re: Decommissioning of Blood Alcohol Instrument 610N0092108

This memorandum is written to document the removal from service of instrument 610N0092108 for use in the Toxicology Blood Alcohol discipline. This instrument is being retired as part of the normal replacement cycle for major instrumentation at the Scottsdale Crime Laboratory.

In keeping with the policies of the Scottsdale Police Department, all records for this instrument as well as all data and other electronic information generated on or for this instrument shall be maintained for a minimum period of 5 years from the above date.

Jennifer S Valdez
Criminalist, Toxicology

olice Department

Certificate of Analysis

Ethanol 0.020 Calibrator

Solution lot	110507-02
Preparation Date	11/05/07
Prepared By	JSV B1149
Method	Gravimetric
Solvent	RO Water
Amount	500 ml
Storage	Working container: room temp Remainder: may be refrigerated

Analysis Method	GC/FID
Calibration Curve	Linear Regression
Number of points	4
Date analyzed	11/07/07
Linearity	0.9999
Calibrators	Cerilliant and Setpoint[1]
Measured value	0.019
Difference from target	0.001
Placed in to use	November 7, 2007
Verified by	JSV B1149 110707

[1] 0.4, 0.2, 0.1, and 0.02 calibrators: Cerilliant lot 35127-81, FN042606-01, Setpoint lot 1113286, and Cerilliant Lot FN030405-01, respectively.

olice Department

Certificate of Analysis

Ethanol 0.100 Calibrator

Solution lot	110507-1
Preparation Date	11/05/07
Prepared By	JSV B1149
Method	Gravimetric
Solvent	RO Water
Amount	500 ml
Storage	Working container: room temp Remainder: may be refrigerated

Analysis Method	GC/FID
Calibration Curve	Linear Regression
Number of points	4
Date analyzed	11/07/07
Linearity	0.9999
Calibrators	Cerilliant and Setpoint[1]
Measured value	0.100, 0.100
% Difference from target	0.0
Placed in to use	November 7, 2007
Verified by	JSV B1149 110707

[1] 0.4, 0.2, 0.1, and 0.02 calibrators: Cerilliant lot 35127-81, FN042606-01, Setpoint lot 1113286, and Cerilliant Lot FN030405-01, respectively.

Police Department
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Police Agency Since 1964

Certificate of Analysis

Ethanol 0.200 Calibrator

Solution lot	110507-2
Preparation Date	11/05/07
Prepared By	JSV B1149
Method	Gravimetric
Solvent	RO Water
Amount	500 ml
Storage	Working container: room temp Remainder: may be refrigerated

Analysis Method	GC/FID
Calibration Curve	Linear Regression
Number of points	4
Date analyzed	11/07/07
Linearity	0.9999
Calibrators	Cerilliant and Setpoint[1]
Measured value	0.205, 0.205
% Difference from target	2.5
Placed in to use	November 7, 2007
Verified by	JSV B1149 110707

[1] 0.4, 0.2, 0.1, and 0.02 calibrators: Cerilliant lot 35127-81, FN042606-01, Setpoint lot 1113286, and Cerilliant Lot FN030405-01, respectively.

olice Department

Certificate of Analysis

Ethanol 0.400 Calibrator

Solution lot	110507-4
Preparation Date	11/05/07
Prepared By	JSV B1149
Method	Gravimetric
Solvent	RO Water
Amount	500 ml
Storage	Working container: room temp Remainder: may be refrigerated

Analysis Method	GC/FID
Calibration Curve	Linear Regression
Number of points	4
Date analyzed	11/07/07
Linearity	0.9999
Calibrators	Cerilliant and Setpoint[1]
Measured value	0.410, 0.400
% Difference from target	2.5 / 0.0
Placed in to use	November 7, 2007
Verified by	JSV B1149 110707

[1] 0.4, 0.2, 0.1, and 0.02 calibrators: Cerilliant lot 35127-81, FN042606-01, Setpoint lot 1113286, and Cerilliant Lot FN030405-01, respectively.

Whole Blood Ethanol Control Level 1

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.

STORAGE AND STABILITY

LiquiSP$_x$ Whole Blood Ethanol Control is stable until the expiration date on the package and 45 days after opening when stored at 2-8° C. This product may be stored frozen; however, it may be frozen and thawed 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.

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. Individual laboratory means should fall within the corresponding expected range.

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 1		Lot No.: XR2902 Exp. Date: 2013/02	
Method	**Units**	**Mean**	**Expected Range**
Gas Chromatography	mg/dL	78.5	72.0-88.0

REFERENCES

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

MANUFACTURED BY
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EC RESPONSIBLE AUTHORITY
CEpartner4U
Esdoornlaan 13
3951 DB Maarn, The Netherlands
P: +31 343 442 524
F: +31 343 442 162
EC REP

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®

33100_00 (3/16/09)

Whole Blood Ethanol Control Level 2

Lot XR2905

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 and 45 days after opening when stored at 2-8° C. This product may be stored frozen; however, it may be frozen and thawed 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.

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. Individual laboratory means should fall within the corresponding expected range.

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		Vial Lot No.: XR2903 Exp. Date: 2013/02	
Method	**Units**	**Mean**	**Expected Range**
Gas Chromatography	mg/dL	194.2	185 - 201

REFERENCES

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

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EC REP

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®

Certificate of Analysis

EMD Chemicals Inc.
480 S. Democrat Road
Gibbstown, NJ 08027
Phone 856-423-6300
Fax 856-423-4389

Name: Ethanol Standard
Ethanol Standard 1.50 mg/mL

Item Number: 68996-95

Lot Number: 8115

Formula: CH_3CH_2OH in water

Formula Wt: 46.07

Data Order No: 000171617

CHARACTERISTIC	REQUIREMENT		RESULTS	UNITS
	Min.	Max.		
Appearance			Passes test	
Assay for Ethanol	1.477	1.538	1.499	mg/mL
Expiration date			31-OCT-2010	
SRM Ethanol-Water Solution			2894	

Jim Morgera,
Quality Control Manager

Release Date: 5/23/2008

EMD Chemicals Inc.
(Formerly EM Science, A Division of EM Industries, Inc.)
An Affiliate of Merck KGaA, Darmstadt, Germany

Cerilliant®
Analytical Reference Standards

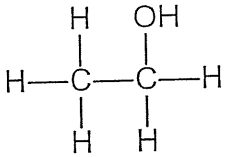
E-056
FN022207-02
Revision 1

ISO GUIDE 34
ACCREDITED
CERTIFICATE AR1353
ISO/IEC 17025
ACCREDITED
CERTIFICATE AT1362
ISO 9001:2000
CERTIFIED
CERTIFICATE 3854

Certificate of Analysis

Ethanol-20

Ethyl alcohol



Catalog Number:	E-056
Solution Lot:	FN022207-02
Expiration Date:	February 2012
Solvent:	Water
Amount per Ampule:	1.2 mL
Storage:	Protect from light, refrigerate.
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	100%	20.00 ± 0.62 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

Standard Solution Comparability

Standard Solution	*Lot Number*	*Concentration* [3] *(mg/dL)*	*% Difference from Target*
New Lot	FN022207-02	20.08	0.4
Previous Lot	FN032206-01	20.07	0.4

Standard Solution Homogeneity

Ampuling Position	*Concentration* [3] *(mg/dL)*	*Mean*	*% RSD*
Early	20.03		
Middle	20.21		
Late	20.01	20.08	0.6

[3] Concentration values are determined by comparison to an independent calibration curve prepared from a NIST ethanol standard (SRM 1828a). 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-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

Calibration Curve:	Linear Regression
Number of Points:	5
Linearity (r):	0.999

Each point analyzed in triplicate

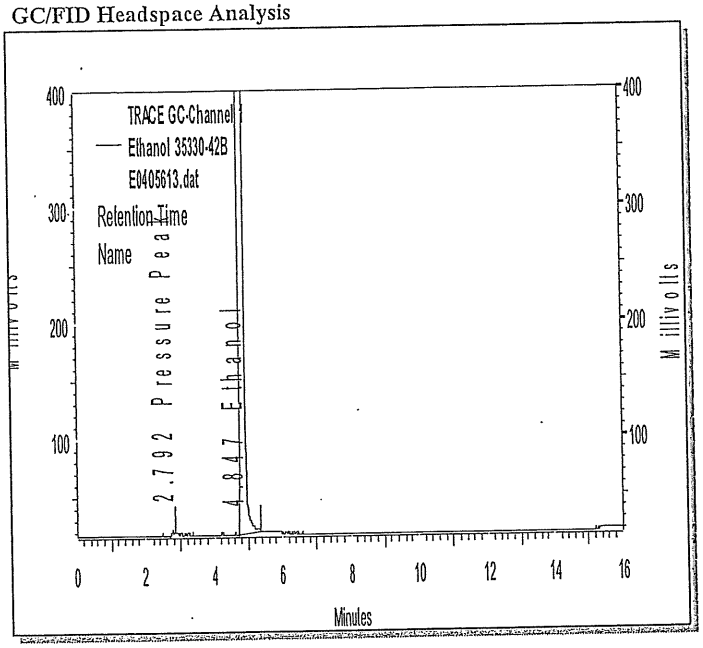
Neat Material Data

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

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

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
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	99.97
Total			99.97

Cerilliant®

Certificate of Analysis

Certified Reference Material - NIST Traceable

Ethanol-20

Ethyl Alcohol

ISO GUIDE 34 ACCREDITED CERTIFICATE AR1353
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

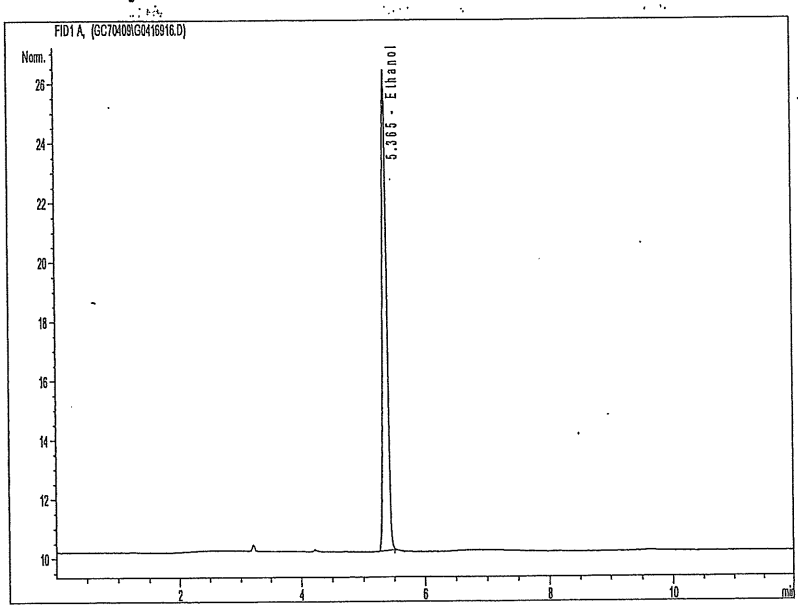
Solution Standard	Lot Number	Concentration (mg/mL)	NIST SRM Lot and Concentration used for Assay	%RSD	
New Lot	FN030409-01	20.41	SRM 2891	1.1%	Homogeneity
Prior Lot	FN022207-02	20.02	0.01951% ± 0.00018%	2.3%	System Suitability

- 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

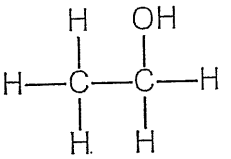
E-045
FN080307-02
Revision 2

ISO GUIDE 34 ACCREDITED
ISO/IEC 17025 ACCREDITED
ISO 9001:2000 CERTIFIED

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

Analytical Verification of Solution Standard Concentration and Homogeneity

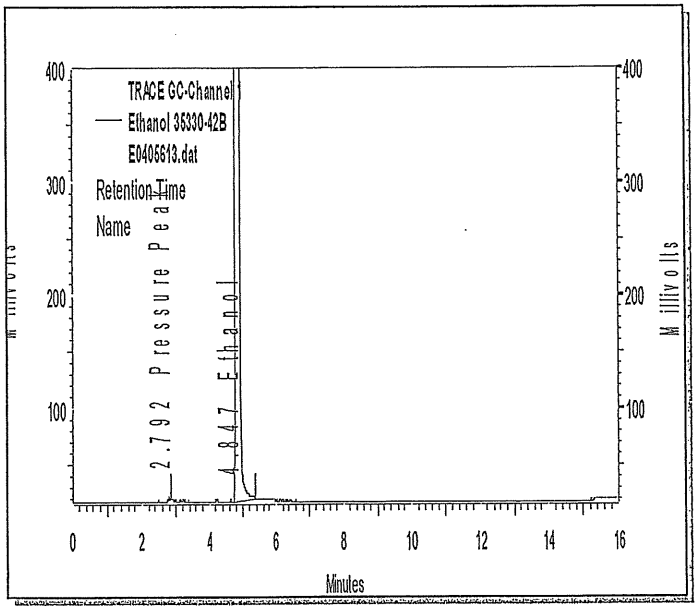
Solution Standard	Lot Number	Concentration (mg/dL)	% Difference from Target	Homogeneity % RSD
New Lot	FN080307-02	40.2	0.5	0.4
Previous Lot	FN082406-01	40.5	1.2	1.3

- 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®
Analytical Reference Standards

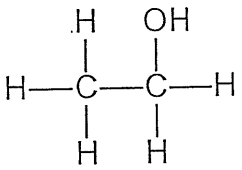
E-053
FN011408-01
Revision 1

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

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	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

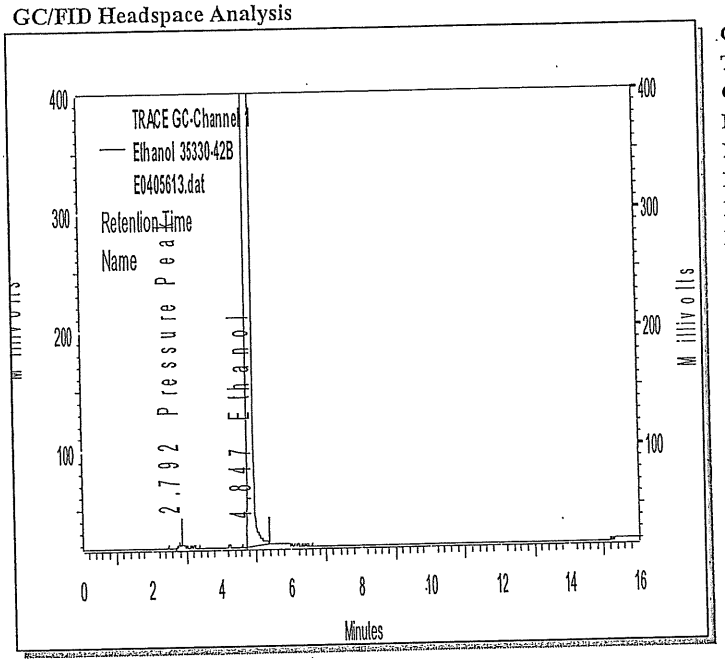
Analysis Method:	GC/FID Headspace	**Calibration Curve:**	Linear Regression
Column:	DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness	**Number of Points:**	4
Temp Program:	40°C hold for 12 min	**Linearity (r):**	0.999
Injector Temp:	200°C		
Detector Temp:	250°C		

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

Cerilliant®
Analytical Reference Standards

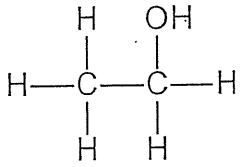
E-041
FN020108-01
Revision 1

ISO GUIDE 34
ACCREDITED
CERTIFICATE AR1353
ISO/IEC 17025
ACCREDITED
CERTIFICATE AR1352
ISO 9001:2000
CERTIFIED
CERTIFICATE 3854

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.

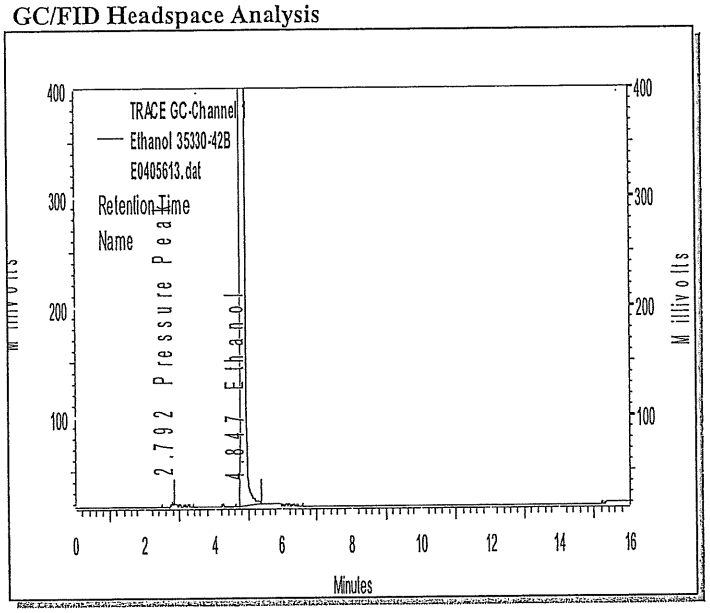
Neat Material Data

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
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CERTIFICATE AR1353
ISO/IEC 17025
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CERTIFICATE AT1352
ISO 9001:2000
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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

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

Analytical Verification of Solution Standard Concentration and Homogeneity

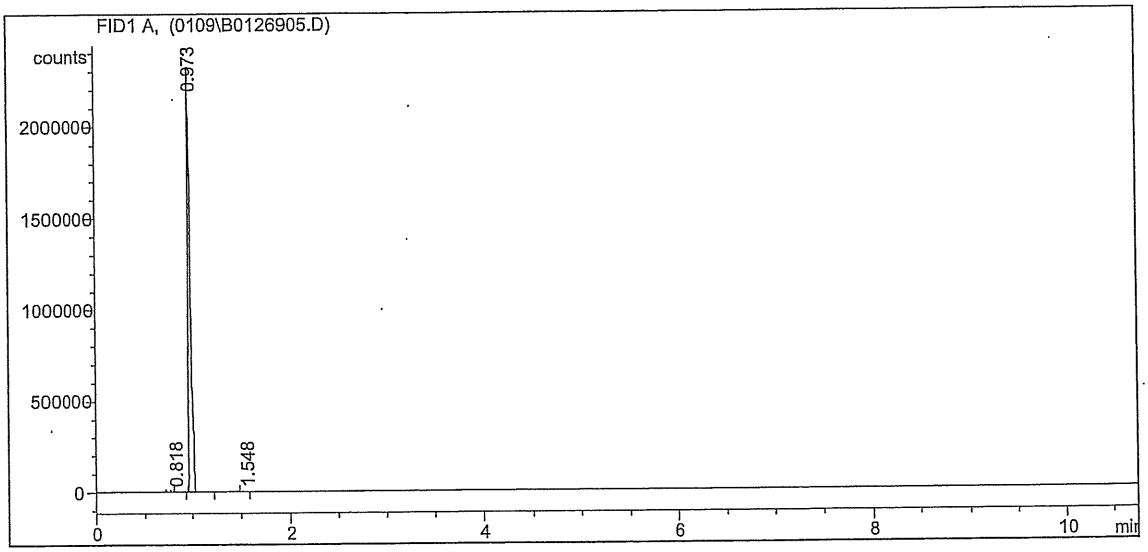
Solution Standard	Lot Number	Concentration (mg/dL)	NIST SRM Lot and Concentration used for Assay	%RSD	
New Lot	FN040909-01	405.0	SRM 2896	1.7%	Homogeneity
Prior Lot	FN092507-01	397.7	0.2980% ± 0.0030%	0.9%	System Suitability

- 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®

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-80

Ethyl Alcohol

ISO GUIDE 34 ACCREDITED CERTIFICATE AR1353
ISO/IEC 17025 ACCREDITED CERTIFICATE AT1353
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

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

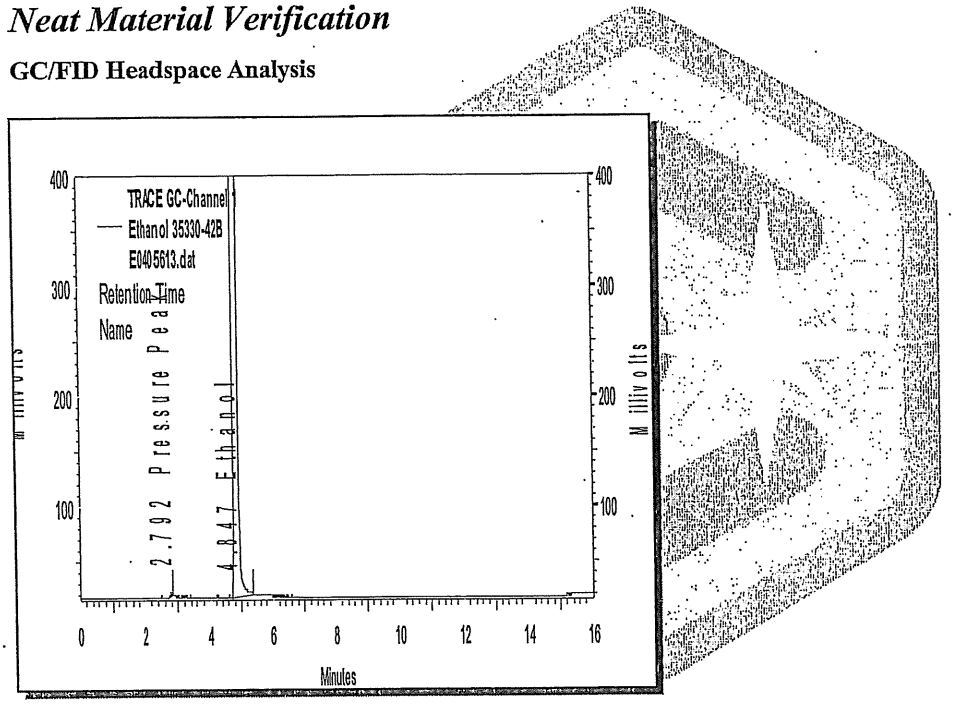
NIST Calibration Curve

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 3854

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

Lara Sparks, Quality Assurance Director

November 5, 2009
Date

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

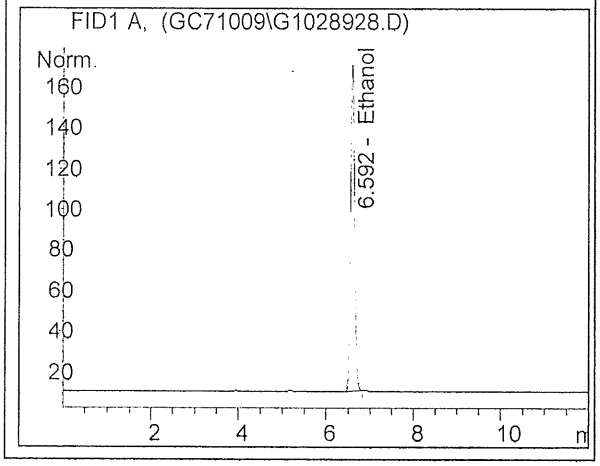
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

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

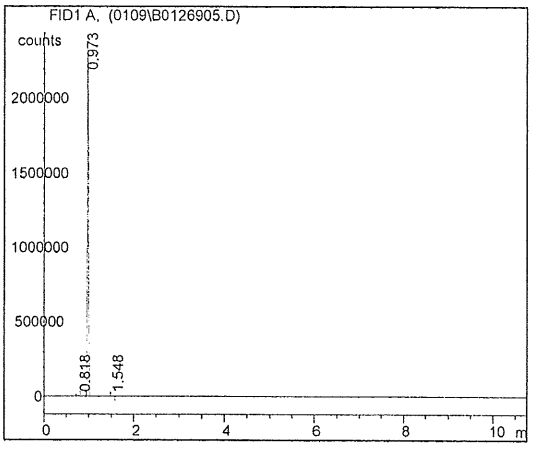
Analysis Method:	GC/FID Headspace
Column:	DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness
Temp Program:	40°C hold for 12 min
Injector Temp:	200°C
Detector Temp:	250°C



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®

ISO GUIDE 34
CERTIFICATE AR1353

ISO/IEC 17025
CERTIFICATE AT1352

ISO 9001:2000
CERTIFICATE 3854

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

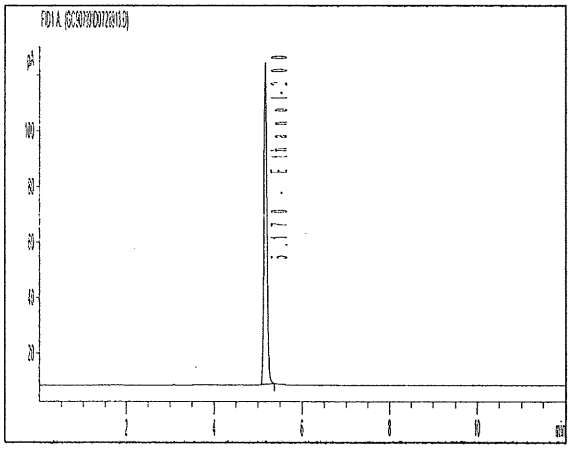
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

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

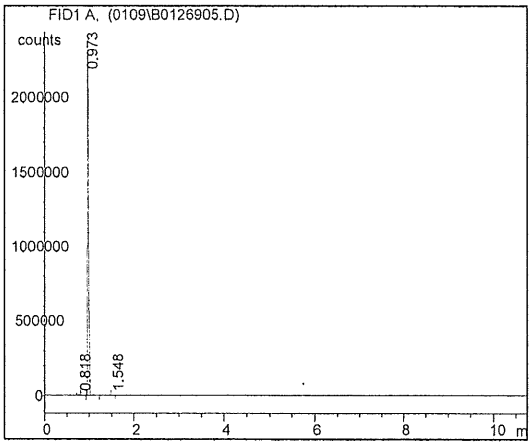
Analysis Method:	GC/FID Headspace
Column:	DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness
Temp Program:	40°C hold for 12 min
Injector Temp:	200°C
Detector Temp:	250°C



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 AR1352

ISO 9001:2000
CERTIFIED
CERTIFICATE 3854

Certificate of Analysis

Certified Reference Material - NIST Traceable

Ethanol-300

Ethyl Alcohol

Catalog Number:	E-033
Solution Lot:	FN052609-03
Expiration Date:	May 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%	300.0 ± 1.1 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

July 10, 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	FN052609-03	296.9	SRM 2896	0.86%	Homogeneity
Prior Lot	FN081507-01	299.8	0.2980% ± 0.0030%	0.68%	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