INTEROFFICE COMMUNICATION

WASHINGTON STATE PATROL

TO: Dr. Barry K. Logan, State Toxicologist

FROM: Sgt. Rod Gullberg, Breath Test Section

SUBJECT: Approval of BAC Datamaster CDM Instrument

DATE: June 30, 2004

The Breath Test Section has been evaluating the BAC Datamaster CDM (National Patent Analytical Systems, Inc., Mansfield, OH) breath test instrument for the past few months. Our evaluation is complete and the summary reports have been provided for your review. The instrument has complied with our existing Quality Assurance Procedure standards and has performed with comparable accuracy and precision to the existing Datamaster instrument in both control standard and human subject testing. The Datamaster CDM is essentially the same instrument as the current Datamaster with both having the same filter frequencies, same software and most of the same hardware components. Based on this information and the results of our evaluation, we are recommending that the BAC Datamaster CDM be identified in the Washington Administrative Code as an approved evidential breath test instrument for use in Washington State.

RGG:rg

Cc: Lt. R. S. Reichert, Implied Consent Section

CDM Approved 6/30/2004

Evaluation of BAC Datamaster CDM Breath Test Instrument

Summary Report

June 30, 2004

Instrument Name:

BAC Datamaster CDM

Serial Numbers:

130155

Manufacturer:

National Patent Analytical Systems, Inc.
Mansfield, OH

Instrument Technology:

Infrared Absorption

Instrument Features:

Same as those now offered in the BAC Datamaster
Additional features beyond the BAC Datamaster:

- External laser printer
- Lighter weight (25 lbs)
- Smaller sample chamber (approx. 40ml)
- Shorter pathlength
- Most printed circuit boards are interchangeable with the Datamaster
- Provision to obtain n=10 subject breath samples for experimental purposes
- Question regarding subject race will now accept all alpha characters

Instrument Evaluation Results

All analyses noted below were performed at the Roanoke office of the Breath Test Section between March and May 2004

Accuracy and Precision:

A complete Quality Assurance Procedure was accomplished on the instrument including replicate measurements (n=10) being performed at four concentrations. The table below lists both the percent systematic error and the percent coefficient of variation (CV) for the instrument.

Alcohol Concentrations (g/210L)

Ref. Value	0.0408	0.0829	0.1044	0.1514
Systematic Error	1.47	2.17	-0.77	0.40
Percent CV	(1.93)	(0.83)	(0.48)	(0.33)

The accuracy and precision estimates complied with the current program policies regarding the Quality Assurance Procedure. In addition, the instrument complied with all other required elements currently required in the Quality Assurance Procedure.

Instrument Recovery Evaluation

The ability of the instrument to recover between extreme sample concentrations was evaluated by introducing both approximate 0.04 and 0.40 g/210L simulator samples in alternating sequence until n=10 measurements were performed at each level. The mean, standard deviation and CV are shown below. The precision was very acceptable showing sufficient recovery between extreme sample measurements. The results were also plotted.

	0.04			**0.44**		
	Mean	SD	CV	Mean	SD	CV
BAC Datamaster CDM	0.0387	0.00048	1.2%	0.4190	0.0013	0.32%

The Variability/Concentration Relationship and Computing Level of Detection (LOD)

Replicate (n=10) samples were introduced from a simulator at several different concentrations, beginning near 0.01 g/210L. The standard deviations were plotted against the sample means. Using the lowest n=10 concentrations, the least squares regression line was computed and used for determining the level of detection (LOD). The LOD was determined according to: $LOD = 3S_0$ (where S_0 = the standard deviation at zero concentration). Least squares regression line for the entire data set is shown below along with the LOD estimation. The results were very acceptable and comparable to the existing BAC Datamaster for which the same data is shown below. The concentration of 0.608 g/210L was the highest reported by the instrument. Higher concentrations were rejected as "Detector Overflow". This provides an estimate of the maximum measurable concentration on the instrument. Plots for both instruments are also included here.

	Least Squares Regression	LOD (g/210L)
BAC Datamaster CDM	SD = 0.0018C + 0.0008	0.0002
Datamaster (949225)	SD = 0.00453C + 0.0003	0.00138

Blank Breath Alcohol Samples

The measurement of blank breath samples (i.e., human breath without alcohol) provide an useful method for evaluating the noise level of an instrument. This was accomplished by introducing n=10 breath samples from a subject with alcohol free breath. One result yielded 0.001 g/210L while all of the others yielded 0.000 g/210L. This is a very acceptable level of response indicating the noise level of the instrument and corresponds to results observed in the existing BAC Datamaster instruments.

Acetone Evaluation

The response of the instrument to the presence of acetone was evaluated using prepared water and acetone solutions used in simulator devices. An attached document shows the calculations and response of the instrument. The results indicated that the instrument would require 642 μg/L of acetone in the vapor phase to yield 0.01 g/210L ethanol equivalent. This is very acceptable with expected levels in diabetics reported in the literature. This concentration also compares with previous tests performed on the BAC Datamaster.

Analyses With Loose Simulator Jars

The effect of having a loose simulator jar was evaluated on the BAC Datamaster CDM along with a BAC Datamaster and other instruments. Replicate (n=5) simulator measurements were performed with tightly sealed jars, one-eighth turn loose jars and one-sixteenth turn loose jars. The mean results (g/210L) are summarized below and the raw data is found on attached documents.

	Intox 8000	**Datamaster**	**Alcotest 7110 IR**	**Datamaster CDM**
Tight Seal	0.070	0.0768	0.0764	0.0706
1/8 turn loose	0.0	0.0762	Error	0.0712
1/16 turn loose	0.0	0.0760	Error	0.0708

Similar to the Datamaster, the Datamaster CDM is not as sensitive to small leaks in the simulator system like other instruments. The Datamaster CDM relies on positive pressure pump system where as the other instruments rely largely on a negative pressure (vacuum) pump system to introduce the simulator vapor sample into the sample chamber. The system employed in the Datamaster CDM has advantages over the other instruments.

Drinking Lab Results

A drinking lab was conducted on May 6, 2004 in which three volunteers consumed specified amounts of an alcoholic beverage and provided a large number of breath samples into all of six different breath test instruments being evaluated. One of the instruments employed in the lab was the BAC Datamaster CDM being discussed here. As part of the lab, replicate simulator standards were measured at two different concentrations (0.04 and 0.08 g/210L) along with replicates (n=10) from each subject into all instruments. Attached figures and a summary report describe the analysis done to determine the components of variance. The Datamaster CDM yielded results that were very acceptable and comparable to the other BAC Datamaster also evaluated.

6/30/2004

Office use only

WASHINGTON STATE PATROL BREATH TEST SECTION
BAC DATAMASTER QUALITY ASSURANCE PROCEDURE
SOFTWARE VERSION 76016

Instrument serial # 130155 CDM **Date** 04/01/04

A. Electrical Checks: within tolerance

1.a)	√					
1.b)	√					
2.a)	√					
2.b)	√					
3.)	√					
4.)	√					
5.)	√					
B.)	√	Calibration				
J.	√	Sim. Temp: 34° (+/-.2)C				
M.1	√	Accurate (+/- 5.00%)				
M.2	√	Precise (+/- 3.00%)				
N.	√	Complete Breath Test				
O.	√	Interferant Test				
P.	√	Filter Error				
Q.	√	Mouth Alcohol Test				

C. Simulator Ethanol Tests (Guth Model 34C)

Conc.	0.04	0.08	0.10	0.15
St. Ref. Value	0.0408	0.0829	0.1044	0.1514
Soln Batch #	04004	04002	03016	04007
	0.043	0.084	0.103	0.151
	0.042	0.085	0.104	0.152
	0.041	0.085	0.104	0.153
	0.042	0.084	0.104	0.152
	0.041	0.086	0.104	0.152
	0.042	0.085	0.104	0.152
	0.041	0.085	0.103	0.152
	0.041	0.085	0.103	0.152
	0.040	0.084	0.103	0.152
	0.041	0.084	0.104	0.152
Mean	0.0414	0.0847	0.1036	0.1520
SD	0.0008	0.0007	0.0005	0.0005
Accuracy %	1.47	2.17	-0.77	0.40
CV%	1.93	0.83	0.48	0.33

R. √ RFI Test

S. √ Diagnostic Test

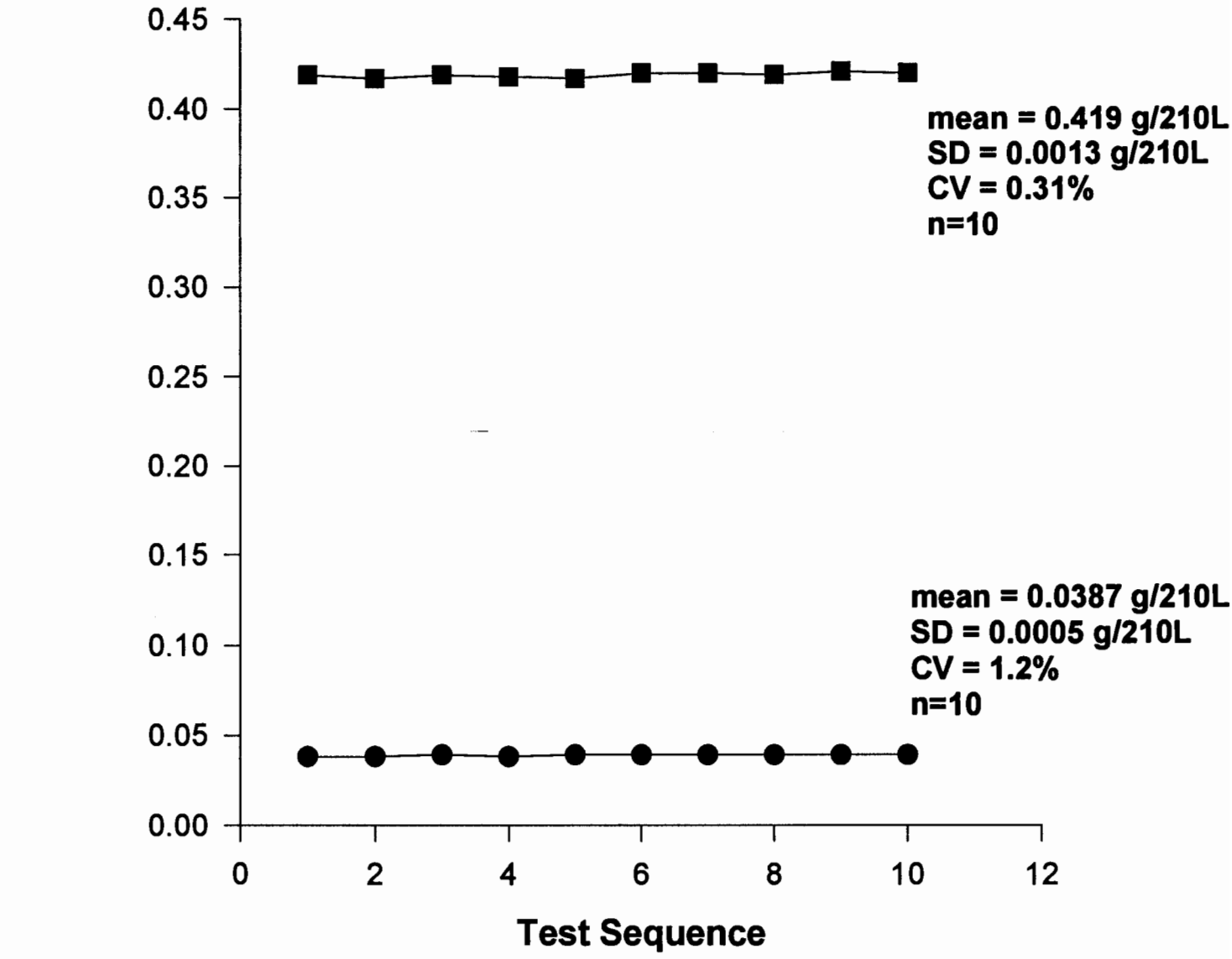
A check mark indicates successful completion of the test, or compliance with Datamaster Quality Assurance Protocol. I swear under penalty of perjury that in regards to the above listed instrument, I have complied with the BAC DataMaster Quality Assurance Procedure (dated:3/24/99) approved by the Washington State Toxicologist.

TPTC STEVE LUCE

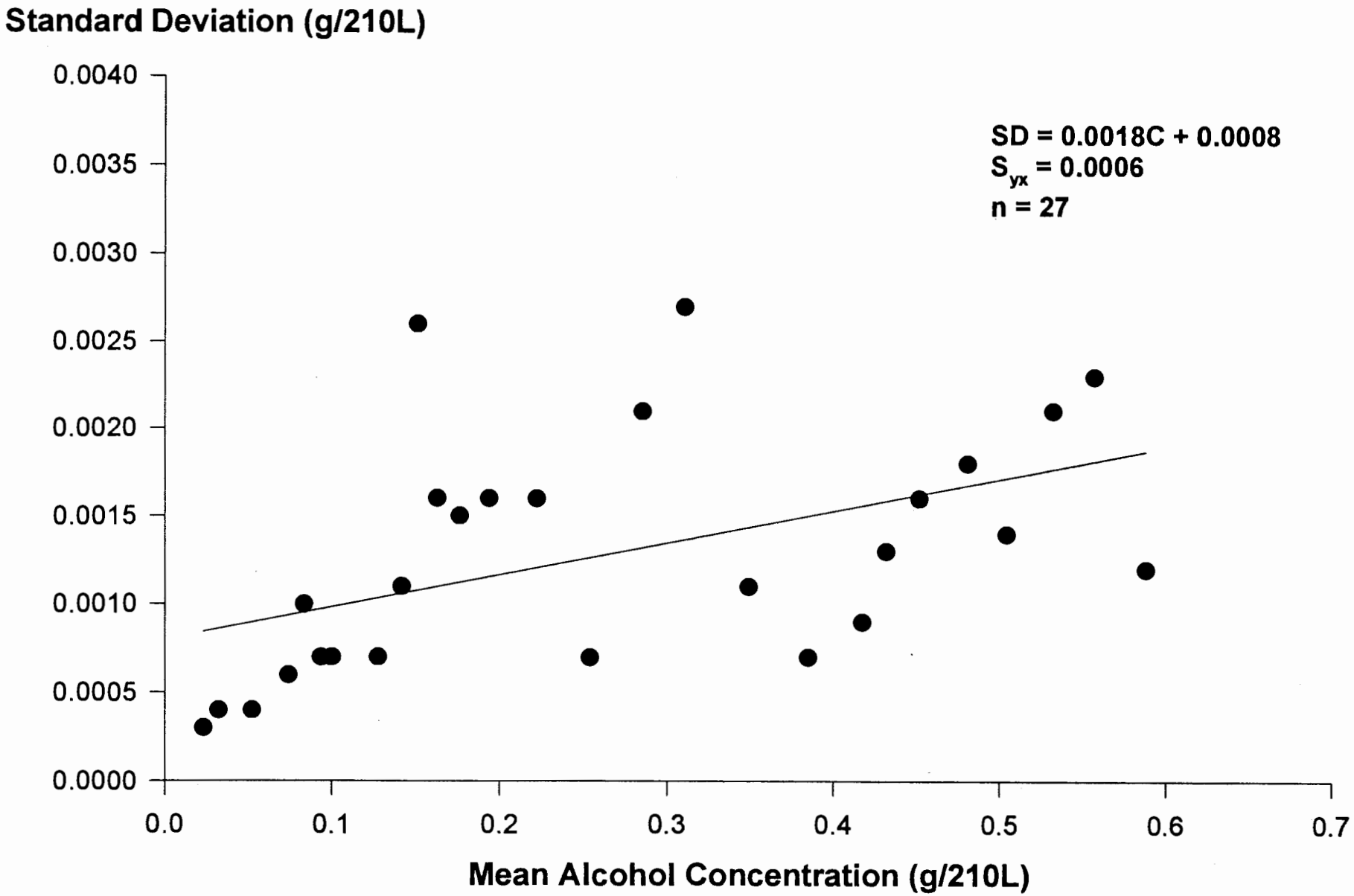
481.BTS

3/31/99

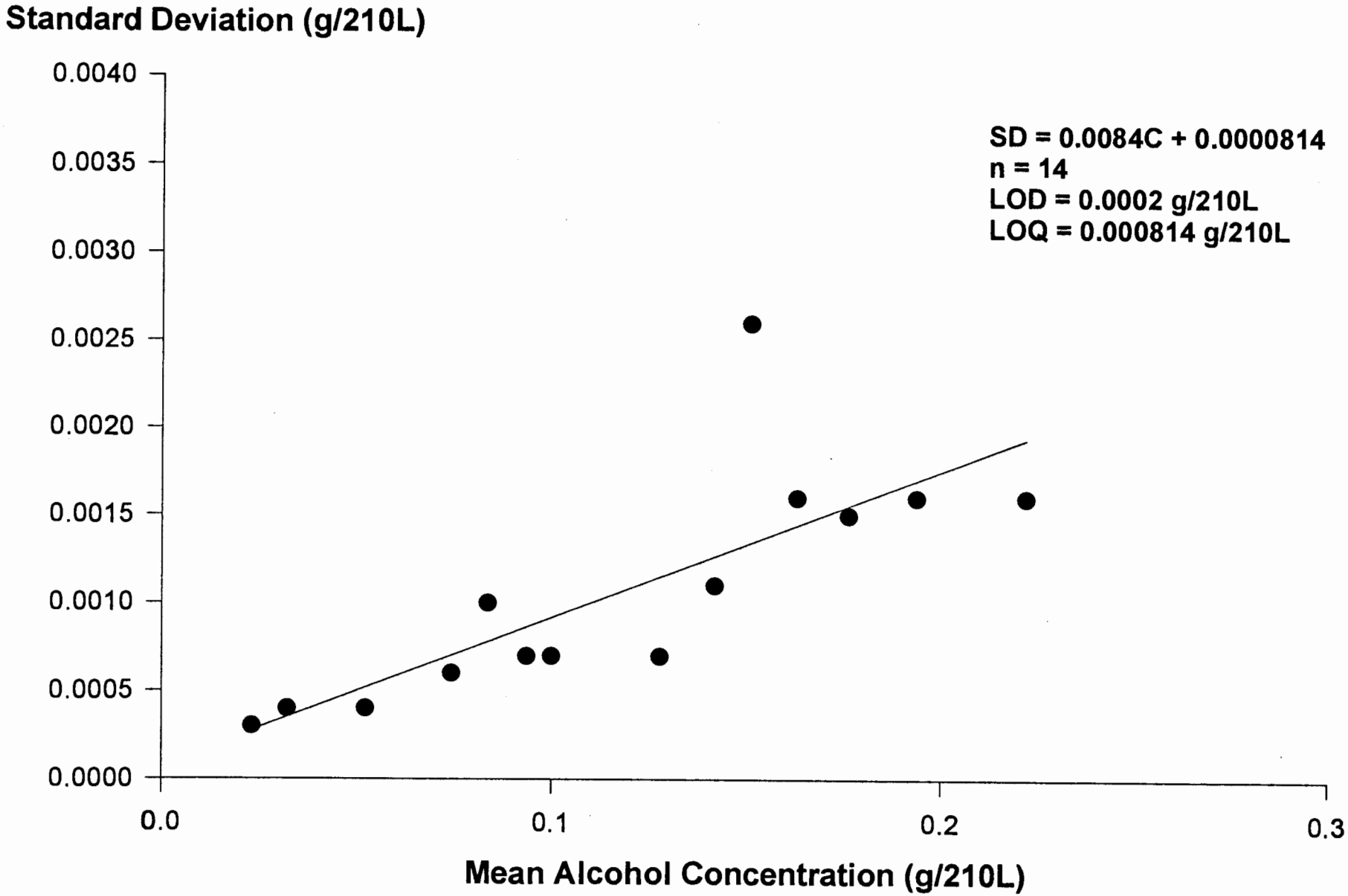
Plot of Results On Datamaster CDM Using Alternating Simulators With Extreme Concentration Differences



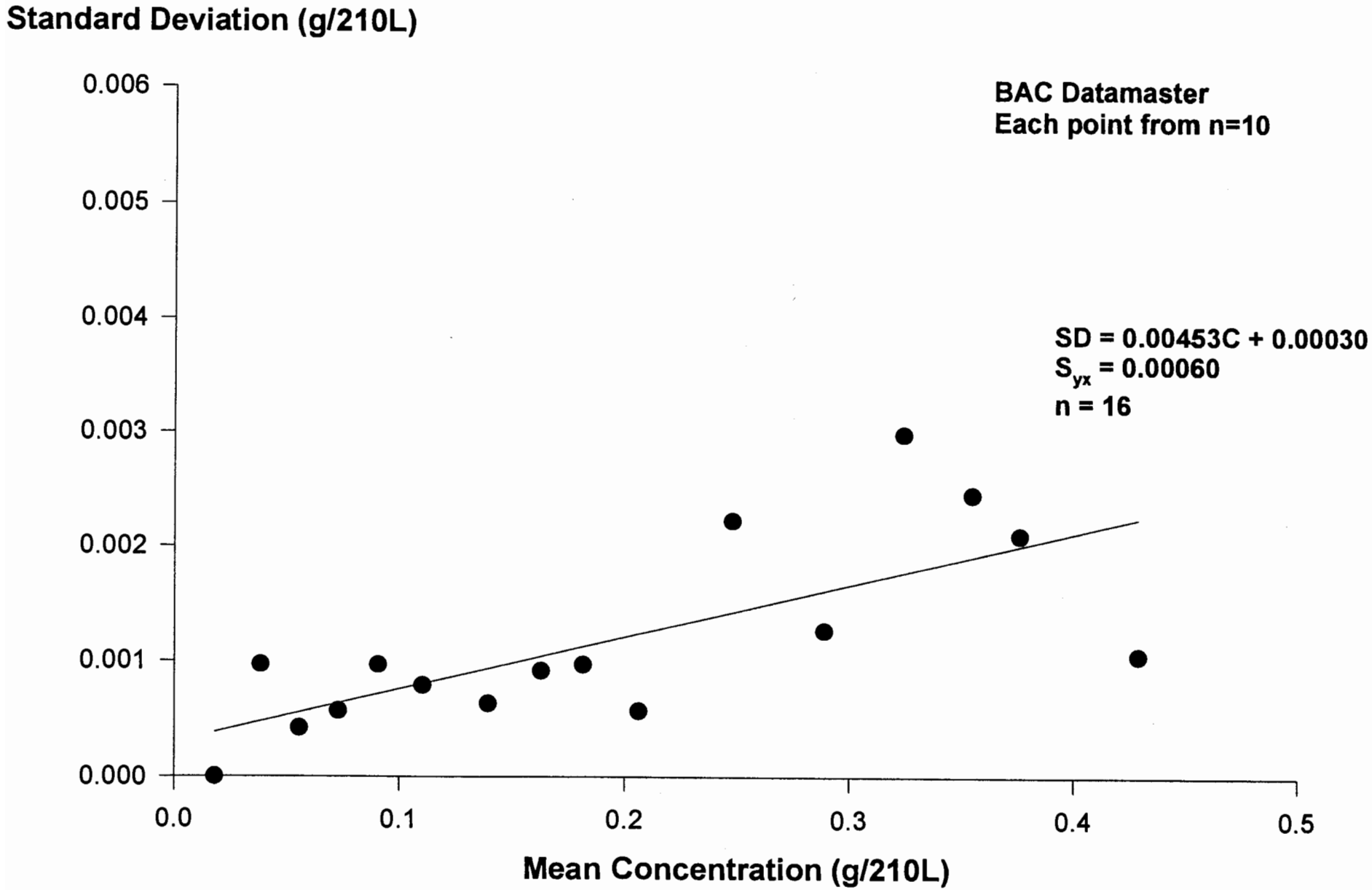
Plot of Standard Deviation Estimates Against Concentration Mean For Replicate Simulator Measurements on Datamaster CDM



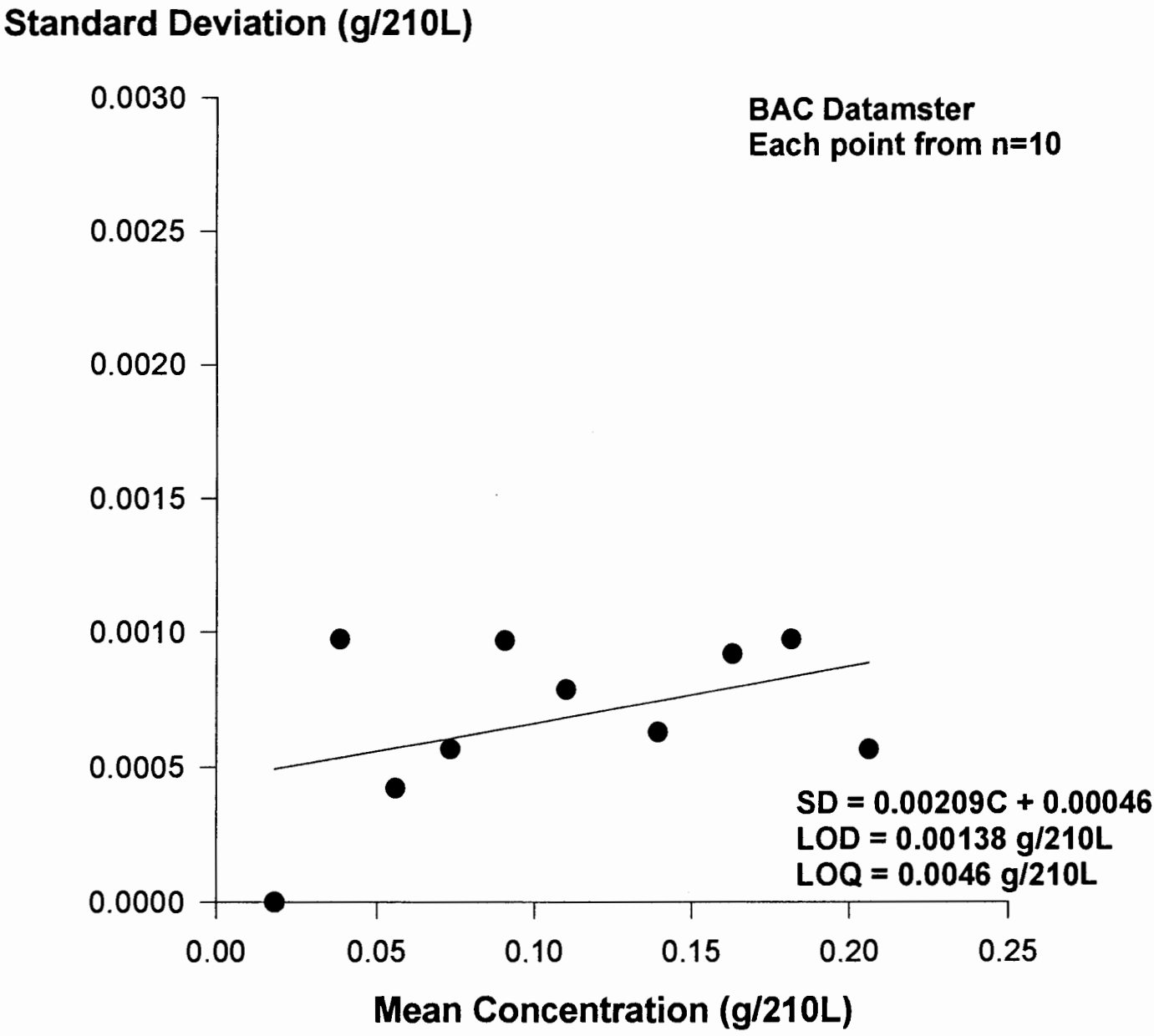
Plot of Standard Deviation Estimates Against Concentration Mean For Replicate Simulator Measurements on Datamaster CDM And Used To Estimate LOD and LOQ



Plot of Standard Deviation Estimates Against Concentration Mean From Simulator Measurements



Plot of Standard Deviation Estimates Against Concentration Mean From Simulator Measurements



Acetone Response on Datamaster CDM

Three measurements were performed on a Datamaster CDM (130155) infrared breath test instrument calibrated accurately to read ethanol as g/210L using a simulator containing 0.5 ml of acetone added to a total volume of 500 ml with water. The results were: 0.036, 0.036 and 0.036 g/210L ethanol equivalent with "Interference Detected" noted on each result. The mean and standard deviation were, 0.0360 g/210L and 0.0 g/210L respectively. The following calculations determine the vapor acetone concentration necessary to yield 0.01 g/210L ethanol equivalent on the instrument.

We begin by computing the grams of acetone per 1 Liter of solution:

$$D_{acetone} = \frac{g}{ml} \Rightarrow 0.789 = \frac{g}{0.5\,ml} \Rightarrow g = 0.3945\,g/500ml \Rightarrow 0.789\,g/L$$

Next, we calculate the vapor concentration of acetone obtained when adding 0.5 ml to 500 ml total solution and heating in a simulator to 34^0 C. We assume the $K_{a/w}$ partition coefficient of acetone in water is 2.931×10^{-3} (Dubowski, K.M. and Essary, N.A., "Response of Breath-Acetone Analyzers to Acetone: Further Studies", Journal of Analytical Toxicology, Vol.8, 1984, pp. 205-208). This is equivalent to $K_{w/a}$ of:

$$K_{w/a} = \frac{1}{K_{a/w}} \Rightarrow K_{w/a} = \frac{1}{2.931x10^{-3}} = \frac{1}{0.002931} = 341$$

We now compute the vapor concentration of acetone in the simulator containing 0.789 g/L in solution and heated to 34^0 C:

$$341 = \frac{0.789\,g/L}{X\,g/L} \Rightarrow X = 0.00231\,g/L = 2310\,\mu g/L$$

We now determine the amount of acetone in the vapor necessary to yield a 0.01 g/210L ethanol equivalent:

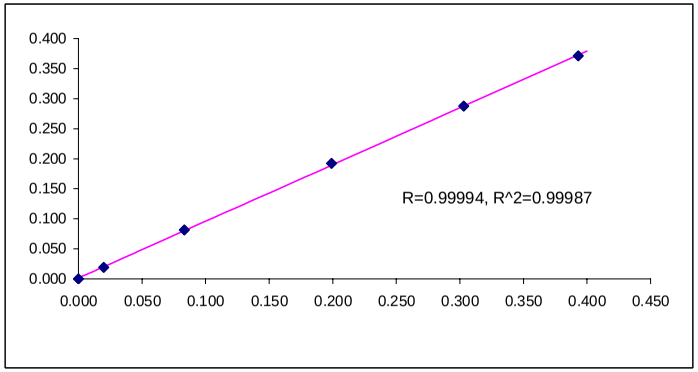
$$\frac{2310\,\mu g/L\,acetone}{0.036\,g/210L\,ethanol\,equiv.} = \frac{X}{0.01\,g/210L\,ethanol\,equiv.} \Rightarrow X = 642\,\mu g/L\,acetone$$

This concentration far exceeds most values reported in the medical literature for uncontrolled diabetic individuals or those fasting and are experiencing ketoacidosis.

4/27/2004

Table 1 Test results for DataMaster CDM 130155

Software version# 76043-004 (04/28/04) Date: 04/28/04 External Batch# 0.0834 (04008)



10 supervisory tests

Reference Concentration (Ethanol) (g/210L)	Reference Concentration (Acetone) (g/210L)	Mean	Standard deviation	Accuracy (%)	Ethanol Precision (CV%)	Interference detected Mean	Standard deviation
0.083	0.000	0.082	0.0008	-0.170	1.008	-	-
0.000	0.000	0.000	0.0003	0.010	0.000	-	-
0.020	0.000	0.019	0.0000	-5.000	0.000	-	-
0.199	0.000	0.192	0.0000	-3.467	0.000	-	-
0.303	0.000	0.288	0.0000	-5.116	0.000	-	-
0.393	0.000	0.371	0.0017	-5.496	0.461	-	-
0.080	0.099	0.088	0.0015	10.250	1.756	-	-

SUMMARY PERFORMANCE DATA	Accuracy	Precision	Slope	Linearity
Standards	**-3.207**	**0.245**	**1.058**	**1.000**

Duplicate breath tests

Reference Concentration (Ethanol) (g/210L)	Reference Concentration (Acetone) (g/210L)	Breath 1	Int.	External standard	Int.	Breath 2	Int.	Ethanol Mean	Ethanol Standard deviation	Interference Mean	Interference Standard deviation	Subject Accuracy (%)	Ethanol Precision (CV%)	External standard accuracy (%)
0.080	0.000	0.083	-	0.081	-	0.077	-	0.080	0.004	-	-	0.00	5.303	-2.878
0.000	0.000	0.000	-	0.082	-	0.000	-	*	*	-	-	*	*	-1.679
0.020	0.000	0.019	-	0.081	-	0.019	-	0.019	0.000	-	-	-5.00	0.000	-2.878
0.199	0.000	0.188	-	0.081	-	0.186	-	0.187	0.001	-	-	-6.03	0.756	-2.878
0.303	0.000	0.276	-	0.082	-	0.279	-	0.278	0.002	-	-	-8.42	0.764	-1.679
0.393	0.000	0.365	-	0.083	-	0.361	-	0.363	0.003	-	-	-7.63	0.779	-0.480
0.080	0.099	0.085	-	0.080	-	0.085	-	0.085	0.000	-	-	6.25	0.000	-4.077

SUMMARY PERFORMANCE DATA	Accuracy	Precision	Slope	Linearity
Subject	**-5.416**	**1.521**	**1.089**	**1.000**
Standard	**-2.078**			

* No ethanol present.
- No interference detected.