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TECHNICAL NOTE

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Robert J. Leonard,[1] *M.S.*

Evaluation of the Analytical Performance of a Fuel Cell Breath Alcohol Testing Instrument: A Seven-Year Comprehensive Study

ABSTRACT: Between 2003 and 2009, 54,255 breath test sequences were performed on 129 AlcoSensor IV–XL evidential instruments in Orange County, CA. The overall mean breath alcohol concentration and standard deviation from these tests was 0.141 ± 0.051 g/210 L. Of these test sequences, 38,580 successfully resulted in two valid breath alcohol results, with 97.5% of these results agreeing within ±0.020 g/210 L of each other and 86.3% within ±0.010 g/210 L. The mean absolute difference between duplicate tests was 0.006 g/210 L with a median of 0.004 g/210 L. Of the 2.5% of duplicate test results that did not agree within ±0.020 g/210 L, 95% of these had a breath alcohol concentration of 0.10 g/210 L or greater and 77% had an alcohol concentration of 0.15 g/210 L or greater. The data indicate that the AlcoSensor IV–XL can measure a breath sample for alcohol concentration with adequate precision even amid the effects of biological variations.

KEYWORDS: forensic science, forensic alcohol, breath alcohol, breathalyzer, precision, fuel cell, AlcoSensor IV

In driving under the influence cases, the use of portable breath alcohol instruments provide the user with the advantage of obtaining a breath result as close to the time of driving as possible. These portable devices commonly utilize electrochemical (fuel cell) technology to analyze a sample of breath for the presence or absence of alcohol. A fuel cell converts alcohol to acetic acid producing a fixed number of electrons proportional to the amount of alcohol present in the sample (1). Fuel cell instruments have the advantage of being specific for alcohols with no measureable reaction to acetone (2,3). While ethanol is the target alcohol in breath testing, a fuel cell instrument will react with other alcohols, such as methanol and isopropanol. Methanol and isopropanol, however, do not cause a significant response on a fuel cell device and are much more toxic than ethanol (4). This means that it is unlikely for a functioning individual to have any measureable concentration of methanol or isopropanol in their system because of the severity of the impairment at low concentrations of these alcohols.

Fuel cell instruments also suffer from the disadvantage of containing no mouth alcohol detector. Mouth alcohol can produce falsely elevated breath alcohol levels that do not accurately reflect the subject's deep lung air. This effect is minimized by including a 15-min observation period prior to any breath test and requiring duplicate testing, often with a 2-min waiting period between tests. Also, requiring an agreement of ±0.020 g/210 L between duplicate tests, as recommended by the National Safety Council Committee on Alcohol and Other Drugs, allows for further assurance that mouth alcohol did not influence a test (5). Duplicate testing also operates to demonstrate precision in the instrument's measurements.

[1]Orange County Crime Laboratory, 320 North Flower Street, Santa Ana, CA 92703.

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In California, as well as most other states, driving under the influence statutes now set forth that it is unlawful for a person who has 0.08% or more, by weight, of alcohol in their blood or breath to drive a vehicle. The majority of states statutes also set forth that breath results should be reported in units of grams per 210 L. This eliminates the need to convert a breath alcohol result to an equivalent blood alcohol result.

There are many biological variables that impact precision in breath alcohol testing, including the subject's breathing pattern, breath temperature and humidity, and breath volume (6–11). These variables are often used in an attempt to describe the inaccuracy of breath alcohol instruments or to discredit the results produced by such instruments (12–14). These arguments can be misleading, as these variables can affect the accuracy of a breath alcohol result when compared to a blood alcohol result, but they will not affect a breath instrument's ability to analyze a breath sample. Although a breath instrument can determine the sample volume, the fuel cell is oblivious to these other biological effects and will analyze whatever sample is introduced, as long as minimum volume requirements are achieved. The accuracy and precision of an instrument is based on the performance capabilities of the instrument itself, and these parameters must be separated from discussions of other topics such as the correlation of blood and breath alcohol results.

The accuracy of fuel cell breath instruments have been demonstrated to be comparable with that obtained by infrared instruments and, to a lesser degree, blood testing (15). Zuba compared subject breath samples using portable fuel cell instruments (Alco-Senor IV and Alcotest 7410; Intoximeters, Inc., St. Louis, MO), stationary infrared instruments (Alcomat [Siemens, Karlsruhe, Germany]; Alkometr A2.0 [AWAT, Warsaw, Poland]) as well as the results from blood analyses (15). The results obtained from the portable devices compared well with the stationary devices having a mean absolute difference of 0.062 ± 0.053 mg/L (15).

As with any scientific measurement, a degree of uncertainty exists in each breath alcohol result. The largest contributors to the uncertainty of a breath alcohol result are biological/sampling variations, accounting for approximately 73% of the total uncertainty (16). Analytical variations, which include electronics, software, device temperature, etc., account for just 10% and the remaining 17% result from traceability and partition coefficient variations (16). It is clear that any significant variation in duplicate breath tests will largely be the result of biological variations. As stated by Gullberg (17), when duplicate breath results show variability in the second decimal place, this difference is the result of variations in the sample source and not instrument imprecision.

The present study sought to evaluate the precision of a portable fuel cell breath instrument, the AlcoSensor IV–XL @Point of Arrest System (Intoximeters, Inc.), as well as its accuracy against a known standard. Using subject breath test data, the magnitude of the effects of biological variations and their effect on duplicate tests, using the required breath test sequence protocol, can be observed. From this data, the effectiveness of this instrument in the field can be determined. This determination was evaluated based on the instruments reproducibility and the magnitude of the differences between duplicate tests performed in the field.

Materials and Methods

This paper presents the results of an evaluation of evidential breath alcohol results obtained with Alco-Sensor IV–XL instruments from January 1, 2003, to December 31, 2009, in Orange County, CA. The Alco-Sensor IV–XL utilizes an electrochemical fuel cell for the analysis of alcohol in a subject's breath sample. The testing protocol in Orange County includes a 15-min deprivation/observation period, a blank check prior to the first breath sample, a sensor blank check between breath samples, mandatory duplicate testing, minimum 2 min wait between samples, 1.5 L minimum breath volume, and a calibration check with an external standard at least every 10 days. Duplicate subject breath samples are recorded to three decimals with a required agreement not to exceed ±0.020 g/210 L, as recommended by the National Safety Council Committee on Alcohol and Other Drugs (5). If this agreement is not achieved, a third breath sample is required and two of the three results must meet the required agreement. The external standards used for testing accuracy are National Institute of Standards and Technology (NIST) traceable dry gas standards of a known ethanol concentration. The external standard checks must be within ±0.010 g/210 L of the known reference value. For the purposes of this study, a negative test sequence is any duplicate test sequence in which both results are <0.010 g/210 L. If an error occurs, the breath test sequence is aborted.

All data are stored in a central database maintained by the Orange County Crime Laboratory. The stored data include, but are not limited to, instrument serial number, operator information, subject information, date and time of test, breath exhalation duration and volume, and the alcohol result obtained in g/210 L.

Results

Accuracy/Mean Data

The accuracy of the instruments were determined using accuracy check data obtained with NIST traceable dry gas reference standards over the time period in question. The instruments are additionally checked for accuracy and linearity on an as needed basis using simulator solutions with alcohol concentrations of approximately 0.04, 0.08, and 0.20 g/210 L. A total of 29,806 analyses were performed on 129 Alco-Sensor IV–XL instruments, and the mean percent bias was determined to be 2.43% using 0.110 g/210 L ± 2% dry gas standards. The percent bias data included obvious outliers and had a range of 0.00–100%, although 99.7% of the data were within the range of 0.00–10.0%.

The mean and standard deviation breath alcohol concentration (calculated using all available subject data, excluding negative test sequences) for tests one, two, and three were determined to be 0.142 ± 0.051 g/210 L (n = 41,231), 0.139 ± 0.050 g/210 L (n = 38,557), and 0.195 ± 0.058 g/210 L (n = 822), respectively, with an overall mean of 0.141 ± 0.051 g/210 L (n = 80,610). The mean breath alcohol concentration for each individual year is listed in Table 1. The frequency of occurrence of breath results within each specific breath alcohol range is illustrated in Fig. 1. This distribution of the range of alcohol concentrations is relatively normal with some positive skewness.

Evidential Test Data

From January 1, 2003, to December 31, 2009, 54,255 evidential breath test sequences were performed on 129 Alco-Sensor IV–XL instruments for a total of 83,591 breath samples. The number of test sequences performed rose quickly from 2003 to 2005 as the program was being implemented, and then leveled off to between 8000 and 9000 test sequences a year during the period of 2006–2009 (Fig. 2). No trend was observed in relation to the number of test sequences performed and the month of the year.

Of the 54,255 test sequences, 1544 were negative for alcohol (i.e., both results <0.01 g/210 L). Of these negative test sequences, 1309 had both results equal to 0.000 g/210 L, while 182 had one test with a result of 0.000 g/210 L with the subsequent test resulting in an error code. Only 53 test sequences had one or both samples with a result >0.000 g/210 L but <0.010 g/210 L.

Error Codes

Of the 54,255 test sequences performed, 14,333 error codes occurred. The meaning of these error codes and their frequency of occurrence are listed in Table 2. Approximately 33% of these error codes were owing to a failure of the subject to provide the minimum required volume for a breath sample of at least 1.5 L. Another 30% were caused by a failure of the air blank or sensor blank check (triggered if any alcohol level above 0.000 g/210 L is detected), and 25% were owing to a test sequence being initiated but not completed (error codes 3, 5, 13, 22, and 23). Radio frequency interference was detected and accounted for 7% of the error codes, and 5% of the error codes were owing to a manual capture being attempted (i.e., an attempt to override the 1.5 L volume

TABLE 1—*Mean breath alcohol concentration each year* from 2003 to 2009.*

	Year						
	2003	2004	2005	2006	2007	2008	2009
Mean (g/210 L)[†]	0.140	0.142	0.142	0.141	0.142	0.141	0.140
SD (g/210 L)	0.052	0.051	0.052	0.051	0.052	0.051	0.051
n	5892	9646	12,230	13,322	12,753	13,895	12,872

*Data do not include negative test results (i.e., test results with alcohol concentration <0.010 g/210 L).

[†]Mean concentrations determined using all result values from that particular year only.

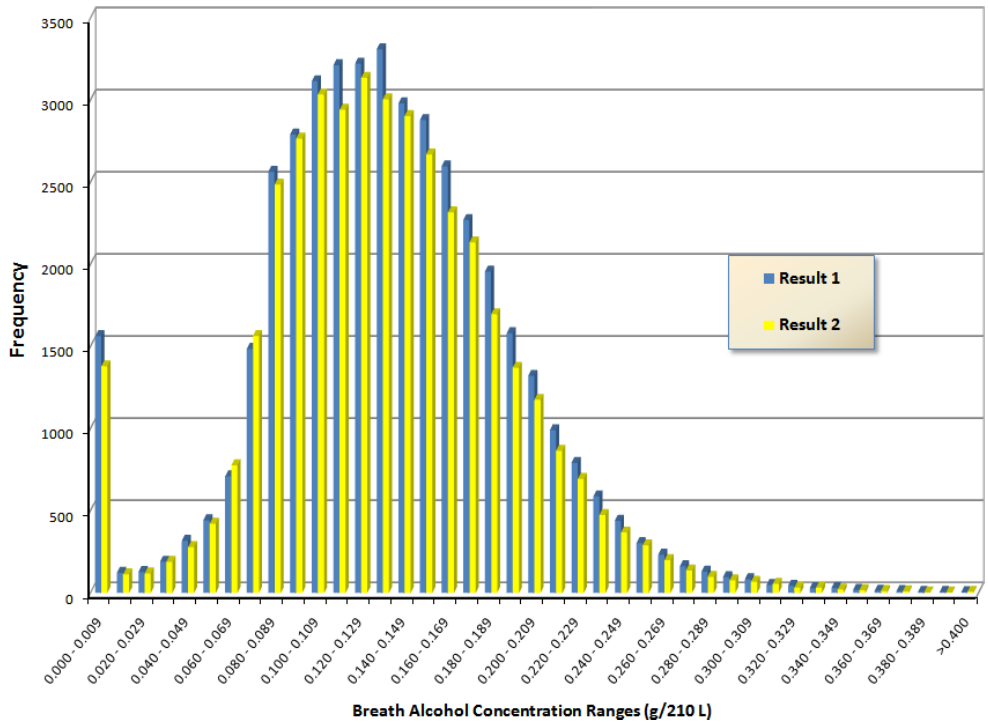

FIG. 1—*Frequency of occurrence of each range of breath alcohol sample concentrations from 2003 to 2009.*

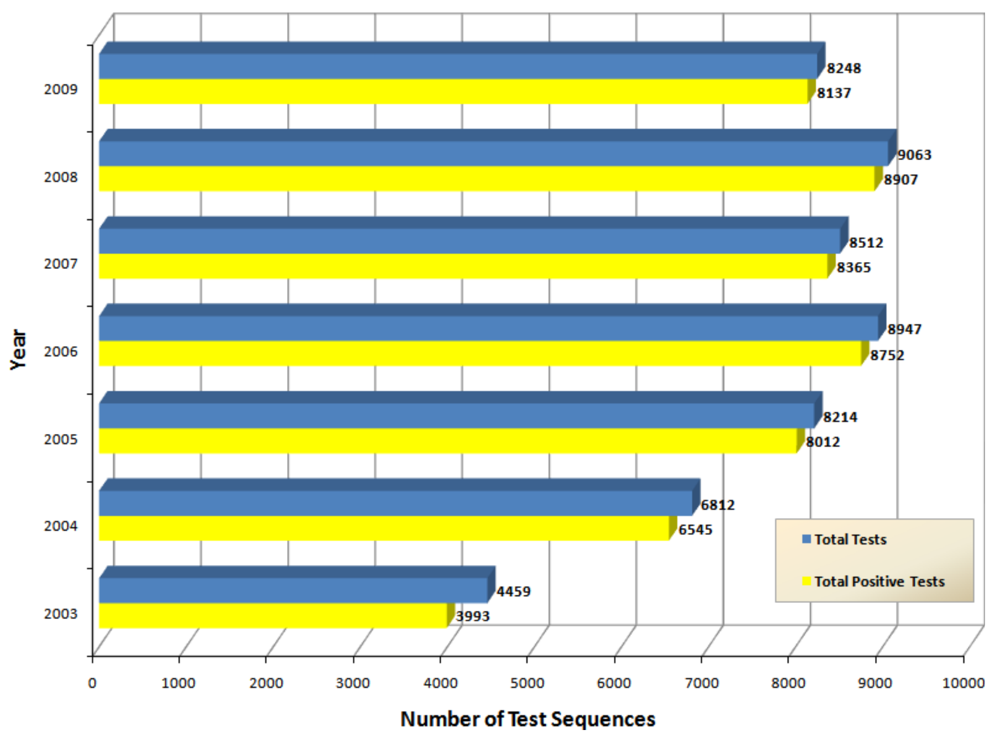

FIG. 2—*Total test sequences performed each year from 2003 to 2009. The top bar for each year represents the number of total tests performed while the bottom bar represents only those tests in which at least one result was >0.01 g/210 L. There were 1544 negative test sequences.*

requirement). The remaining seven possible error codes collectively represent just over 1% of the error codes. In 2890 test sequences, a single error code occurred along with at least one breath alcohol result, while 11,440 test sequences contained only a single error code. Three test sequences contained multiple error codes.

Precision/Duplicate Testing

Of the 54,255 total test sequences, 38,580 resulted in at least two positive breath alcohol results. Of these, 37,631 test sequences (97.5%) successfully resulted in two tests that agreed within

TABLE 2—*Frequency of occurrence of all possible error codes during 2003–2009.*

Error Code*	Reason	Frequency	Percentage of Total
6	Volume insufficient	4659	32.5
11	Blank too high	4275	29.8
5	Test timeout†	1601	11.2
22	Test not completed‡	1409	9.8
12	RFI detected	973	6.8
8	Manual button hit	742	5.2
13	Test timeout§	254	1.8
3	Test refused	178	1.2
23	Test aborted	91	0.6
4	No sample	48	0.3
15	Short blow time	46	0.3
9	Low temperature	21	0.1
1	Low battery	19	0.1
10	High temperature	14	0.1
2	Manual button hit	2	0.0
20	Signal exceeded capacity	1	0.0
		14,333	100

RFI, radio frequency interference.

*Error codes 7 and 14–19 do not exist.

†Error code 5 occurs when the instrument is shut down while the instrument is ready to accept a sample.

‡Error code 22 occurs when the power is shut down prior to authorizing the first test.

§Error code 13 occurs when one test has been completed, but the unit is shut down prior to authorizing the second test.

TABLE 3—*Absolute difference between duplicate test data.*

	Mean*	Median*	SD*	*n*	Range*
All tests†	0.006	0.004	0.009	40,015	0.000–0.332
All tests (no negatives)†	0.006	0.004	0.007	38,580	0.000–0.332
All tests (no negatives/ no thirds)	0.005	0.004	0.004	37,627	0.000–0.020

*All results in units of g/210 L.

†Data include test sequences that required a third test, but only the absolute difference between tests one and two is included in the data.

±0.020 g/210 L of each other. The remaining 949 test sequences, or 2.5%, did not agree within ±0.020 g/210 L and resulted in a required third test.

A summary of basic descriptive statistics regarding the absolute difference between duplicate tests is shown in Table 3. The mean absolute difference between duplicate tests was found to be 0.006 g/210 L while the median absolute difference was 0.004 g/210 L. Figure 3 illustrates the magnitude of agreement between duplicate tests as well as their frequency of occurrence. Duplicate test sequences agreed within ±0.010 g/210 L of each other in 86.3% of all test sequences, within ±0.005 g/210 L of each other in 63.1% of all test sequences, and within ±0.001 g/210 L of each other 20.6% of all test sequences. Duplicate test sequences agreed to three decimals, and thus had no deviation, in 7.1% of all test sequences.

The first two test results did not agree within ±0.020 g/210 L of each other in 949 test sequences and thus required a third test to be performed because of this disparity. Of these third tests, 830 agreed within ±0.020 g/210 L of either the first or second test result. Of the remaining tests, 102 resulted in an error code during the third test and just 17 test sequences had results in which none of the three tests agreed within ±0.020 g/210 L.

For sequences that required a third test, the higher alcohol concentration was associated with a greater breath volume in 690 of the 949 test sequences, or 73% of the time. Compare that to sequences in which only two tests were required where the higher alcohol concentration was associated with a greater breath volume in just 55% of the test sequences. Of the 690 test sequences where the higher volume resulted in a higher breath alcohol concentration, 73% had a volume difference between tests of 500 mL or greater and 47% had a volume difference of at least 1.0 L. Table 4 shows the number of tests in which the higher volume resulted in a higher breath alcohol concentration as well as the corresponding volume difference. Figure 4 plots the single measurement standard deviation against breath alcohol concentration. Only data having mean values ≥0.01 g/210 L are represented. Duplicate tests with mean values within 0.01 g/210 L intervals were combined to form a pooled estimate of a single measurement standard deviation. Similarly, Fig. 5 illustrates the variation in absolute test difference as a function of the mean breath alcohol concentration of the duplicate results.

Additionally, of these 949 test sequences requiring a third test, 95% had a breath alcohol concentration of >0.10 g/210 L and 77% had a concentration >0.15 g/210 L. The average breath alcohol concentration for test sequences in which a third test was required was 0.200, 0.195, and 0.193 for result 1, result 2, and result 3, respectively.

Discussion

The purpose of this evaluation of breath alcohol data between 2003 and 2009 was to observe the precision or imprecision of duplicate testing using portable fuel cell instruments and to evaluate the effectiveness of current procedures, including the 15-min observation period and the minimum breath volume requirement and thus the reliability of these instruments used in the field. This reliability includes the instruments ability to measure a subject's breath alcohol concentration with accuracy and precision. Over the 7-year period in which the data were collected, 54,255 evidential test sequences were performed and provided a substantial amount of data to analyze.

The Alco-Sensor IV–XL is designed to ensure the reliability of the breath alcohol results. When specifications are not met, an error code results. A total of 14,333 error codes occurred. Subjects who did not provide the required minimum volume of 1.5 L of breath accounted for 33% of the error codes. The minimum sample volume requirement ensures that the breath alcohol measurement is made with "essentially alveolar air." This error code can be produced by a subject huffing, placing their tongue on the mouthpiece, or simply not providing adequate volume. Another 30% of the error codes were owing to a blank check failure. No test is allowed to proceed when a blank check detects any alcohol above 0.000 g/210 L. A blank check occurs before every breath sample and ensures that there is no carryover or false positives. Failures commonly occur after repeated use on alcohol positive individuals without allowing sufficient time for the previous sample to dissipate from the fuel cell or when operating the instrument in close proximity to alcohol positive individuals. The next set of frequently occurring error codes comprised 25% of the total and was owing to a test sequence not being completed (error codes 3, 5, 13, 22 and 23, Table 2). The reasons for a test sequence not being completed can vary from a subject refusing or not being physically able to provide a sample, the officer deciding to not proceed with the remainder of the test for the subject's safety or a subject violating the required 15-min observation period by belching, vomiting,

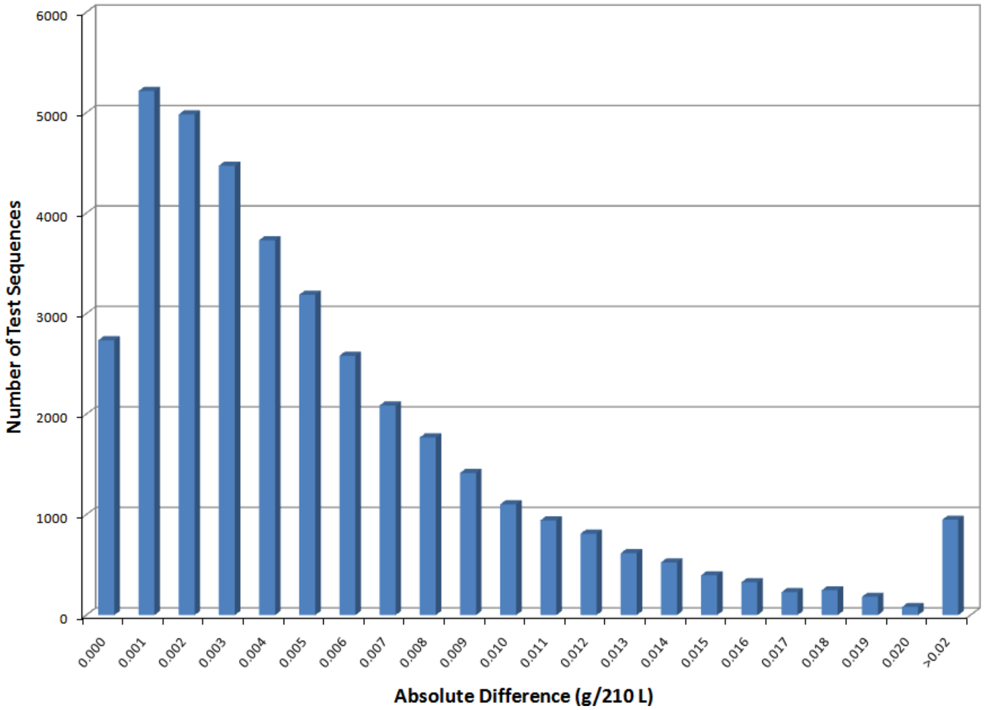

FIG. 3—*Illustration of the absolute difference between duplicate breath tests.*

TABLE 4—*Number of test sequences requiring a third test in which the higher volume resulted in a higher breath alcohol concentration.*

Volume Difference (L)*	*n*	Percentage of Total
2.0+	115	16.7
1.5+	206	29.9
1.0+	324	47.0
0.5+	504	73.0
All	690	100.0

*The volume difference represents the absolute differences in volume between test one and two. The volume differences included in this data table represent only those test sequences in which a third test was required, and the greater breath volume resulted in a higher breath alcohol concentration.

regurgitating, eating or drinking, or placing something in their mouth. If the 15-min observation period is violated, the officer has the option of restarting a new observation period or obtaining a blood sample. These error codes occur when a test is authorized but never completed and the test "times out." The last two frequently occurring error codes were owing to radio frequency interference and attempts to manually capture a breath sample. Radio frequency interference, which may possibly cause interference with the instruments hardware, accounted for 7% of the error codes. This generally occurs if the instrument is operated near cell phone towers or if an officer's attempts to use his radio during the test sequence. The Alco-Sensor IV–XL also does not allow an officer to manually capture a sample, which is an attempt to analyze a sample prior to satisfying the 1.5 L requirement. This occurred in 5% of all error codes and is not allowed to ensure that "essentially alveolar air" is collected and analyzed. A sample that is not alveolar air will almost always result in a breath alcohol concentration that will underestimate the subject's actual blood alcohol concentration. The presence of an error code almost always means that the instrument is functioning properly.

The instruments were determined to have a mean percent bias of 2.43% at an alcohol concentration of 0.110 g/210 L. It is important to note that this value describes the mean accuracy of the instruments using a NIST traceable dry gas standard at an alcohol concentration of 0.110 g/210 L ± 2%, and in no way represents the accuracy of the entire range of alcohol concentrations or the accuracy of any individual subject breath sample when compared to a subject's blood sample.

The mean breath alcohol concentration using 7 years of data, excluding all negative tests, was 0.141 g/210 L for test one and 0.139 g/210 L for test two, with an overall mean of 0.141 g/210 L. The reasoning for the exclusion of values <0.010 g/210 L was to prevent the mean from being skewed by negative tests. The mean breath alcohol concentration for each individual year was consistent with the overall mean, ranging from 0.140 to 0.142 g/210 L, which is almost double the statutory legal limit for drivers in the United States of 0.080 g/210 L. The mean breath alcohol concentration for test three was 0.194 g/210 L, and demonstrated that test sequences which required a third test were most often those of higher alcohol concentration. Of the test sequences in which a third test was required, 95% of the time the first two tests had a breath alcohol concentration of >0.10 g/210 L and 77% of the time greater they had a breath alcohol concentration >0.15 g/210 L. It is evident that the ±0.020 g/210 L requirement becomes much more difficult to satisfy as the alcohol concentration increases because the variability between samples increases as the alcohol concentration increases (Figs 4 and 5). It may be beneficial to adopt a percent agreement system over the entire concentration range to combat this problem (i.e., 10% agreement). Thus, under the static ±0.020 g/210 L agreement requirement, the higher a person's breath alcohol concentration, the more likely a third test will be required.

The main objective of this study was to evaluate the precision of duplicate testing using Alco-Sensor IV–XL portable breath alcohol devices. Of 38,580 duplicate test sequences, 97.5% showed deviations of less than ±0.020 g/210 L, a slight improvement from the 94% reported by Gullberg (18) using an infrared breath testing instrument (although this difference may be attributed to Gullberg's

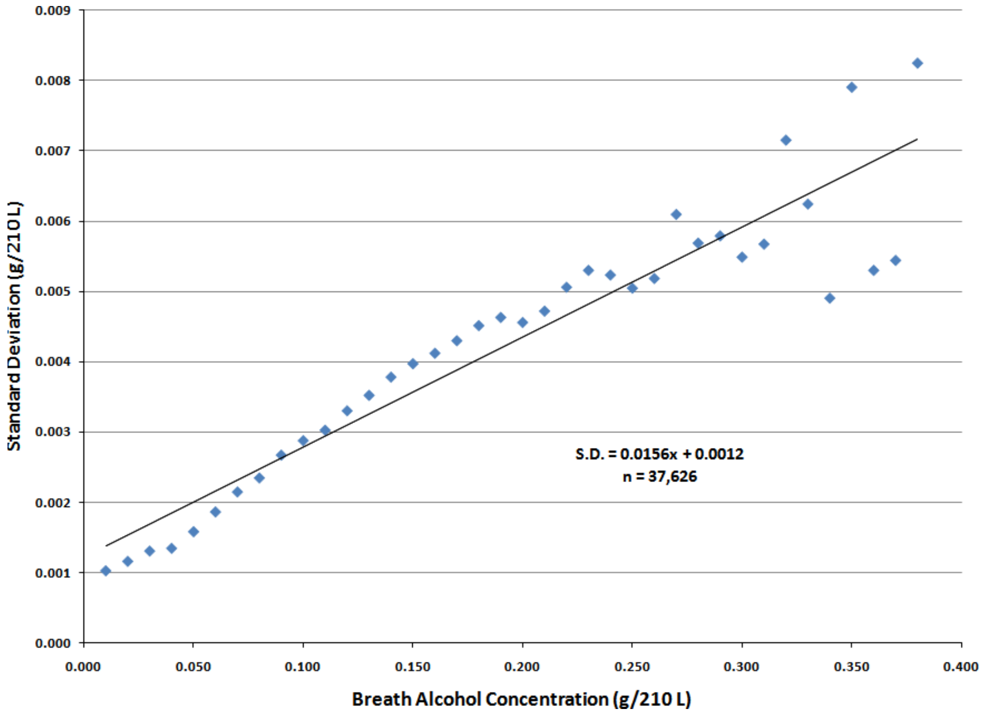

FIG. 4—*Variability of duplicate tests as a function of concentration. Breath alcohol concentrations in 0.01 g/210 L intervals were combined as a single data point and the mean standard deviation of the duplicate tests were used.*

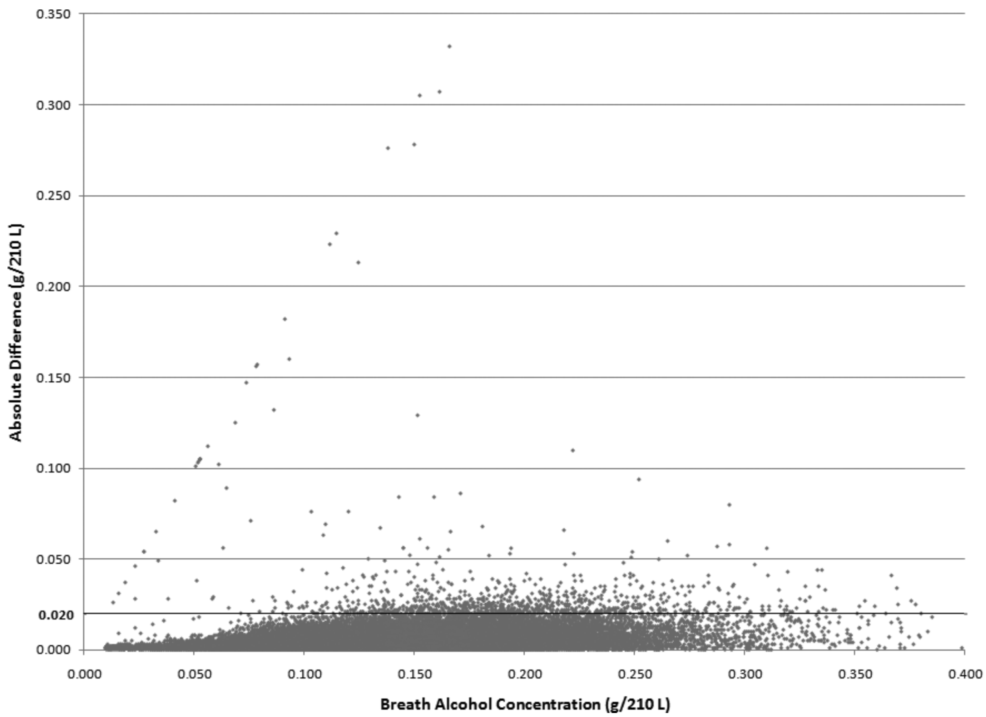

FIG. 5—*Variation in absolute test difference as a function of the mean breath alcohol concentration of the duplicate results. All data is included, even obvious outliers. The line at 0.02 g/210 L represents the required agreement between duplicate tests.*

exclusion of breath test values <0.02 g/210 L). Only 2.5% of test sequences performed over the 7-year period had duplicate results that did not satisfy the required ±0.020 g/210 L agreement. Similar results were reported by Wigmore et al. (19) where only 2% of corrected duplicate tests were not within ±0.020 g/210 L of each other. In the present study, the mean absolute deviation between duplicate tests was 0.006 g/210 L while the median was 0.004 g/210 L. The median value is less affected by outliers that will influence the mean and thus is a better measure of the central tendency in duplicate test differences.

Duplicate testing is meant to ensure precision in the results obtained. Over the period of 7 years, the Alco-Sensor IV–XL demonstrated the ability to produce results well within the required precision limits. In fact, the majority of test sequences (86.3%) had agreements within ±0.010 g/210 L with 63.1% being within ±0.005 g/210 L and 45.1% within ±0.003 g/210 L. The practice of truncating to two digits is common in forensic alcohol testing, and the ability of these instruments to operate with precision to the third digit strengthens the reliability of the two digit truncated result ultimately reported. Even more impressive, only 17 test sequences of a total 38,580 (0.04%) resulted in three tests results, none of which agreed within ±0.020 g/210 L of each other.

It is generally understood in breath alcohol testing that as a person provides a breath sample, their breath alcohol concentration will increase with volume until alveolar air is obtained and a plateau is reached (6,8). This means that a low volume breath sample likely will result in a falsely low breath alcohol concentration compared with a greater volume breath sample if the plateau has not been reached. In 73% of the test sequences that did not agree within the required ±0.020 g/210 L, the higher alcohol concentration also was associated with a greater volume. Moreover, 73% of these had volume differences of 500 mL or greater and 47% had a volume difference of 1.0 L or greater. While this does not indicate that the breath sample volume was the sole reason for the deviation in the duplicate results, it certainly is one possible, if not the most likely, explanation.

Conclusions

This study demonstrates that the use of a portable fuel cell instrument in the field is capable of producing very precise results well within required limits. Uncertainty exists with these measurements as with any measurement, with the largest contributor in breath testing coming from biological or sampling variations such as breathing pattern, breath temperature and humidity, and breath volume. Despite the impact that each of these variables can potentially have on the alcohol concentration of a breath sample, duplicate tests still agreed within ±0.020 g/210 L of each other in 97.5% of all tests performed over a 7-year period, and within ±0.010 g/210 L of each other in 86.3% over the same period. These results demonstrate the exceptional precision of duplicate tests by a fuel cell instrument (and specifically the precision of the AlcoSensor IV–XL) in measuring breath samples for alcohol.

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Additional information and reprint requests:
Robert J. Leonard, M.S.
335 W. Ponce de Leon Ave, #211
Atlanta, GA 30030
E-mail: rleonard20@gmail.com