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Laboratory Testing of Alcoscan Saliva-Alcohol Test Strips

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Data for this project were collected by Dr. Flores at the Transportation Systems Center in Cambridge, MA. Design and report preparation were completed by Dr. Frank at NHTSA.

16. Abstract

This report describes a laboratory evaluation of Alcoscan saliva-alcohol test strips. The objectives of this work were: (1) to determine the precision and accuracy of the Alcoscan strips; and (2) to determine what effect extreme ambient temperatures have on test strip performance. The strips were saturated with alcohol-spiked saliva samples ranging in concentration from 0.03% - 0.12% BAC.

In a highway safety context, the high variability in BAC estimates obtained, coupled with a high proportion of false positives, suggest that this technology is not satisfactory as a screening device for law enforcement. Use by private individuals appears more promising, if the device is not used at low ambient temperatures. At room temperature and above, the chance is relatively low that the rating will falsely indicate that an individual is below the legal limit when he is not. However, given the large variability in rating accuracy at all BAC levels, the utility of the device, even for private citizens, is subject to question.

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LABORATORY TESTING OF ALCOSCAN SALIVA-ALCOHOL TEST STRIPS [1]

James F. Frank and Arthur L. Flores

Introduction

Developing inexpensive, easy to use, portable devices to estimate how much alcohol is in a drinker's bloodstream has been a desired goal for many years. Of course, such devices must also be both reliable and valid if they are to be of any use. Most such equipment developed to date attempts to measure the alcohol content of deep lung breath samples as a way of estimating blood alcohol content. Such devices have been used by police to estimate how much alcohol a suspected drinking driver has in his/her system, as well as for other personal uses by individuals interested in how high their blood alcohol content is. Recent technology advancements have enabled the development of a new technique for measuring saliva alcohol concentration as another way of estimating blood alcohol concentration (BAC).

A California firm, LIFESCAN, Inc. (Mountain View, CA), has developed a test strip, known by the tradename ALCOSCAN, that responds to the presence of alcohol when mixed saliva is put on it.[2] A small 5 X 5 mm square patch on the end of each 4.5 X 0.5 cm Alcoscan strip is treated with the enzyme Alcohol Oxidase, which responds to alcohol in proportion to the concentration of alcohol in a mixed saliva sample placed on it. An ALCOSCAN user estimates a BAC by comparing the color change on the test strip patch to standard colors calibrated to correspond to different BACs.

The objectives of this laboratory research were:

1) to determine the precision and accuracy of the ALCOSCAN strips. The strips were saturated with alcohol-spiked saliva samples ranging in concentration from 0.03-0.12% BAC.

2) to determine what effect extreme ambient temperatures have on test strip performance.

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[1] The data on which this report is based were collected for NHTSA by Dr. Arthur L. Flores of the Transportation Systems Center, U.S. Department of Transportation, Cambridge, MA 02142.

[2] For all practical purposes, the manufacturer has assumed saliva-alcohol concentration to be equivalent to blood-alcohol concentration. The scientific literature indicates that the saliva/blood ratio is 1.082/1 (see Jones, A. W., 1979a, 1979b, 1981). However, given the gross estimates being made when the Alcoscan strips are being used, this slight difference between saliva-alcohol and blood-alcohol concentrations is not significant. For the purposes of this paper, saliva- and blood-alcohol concentrations are equated.

Method

Preparation of Spiked Saliva Samples

Mixed saliva was collected on a daily basis from one of the laboratory personnel conducting the study. He was able to produce approximately 30-40 cc. of fluid daily. Saliva was always used in the experiment on the same day it was collected; it was never stored overnight.

Saliva samples spiked at one of five different alcohol concentrations were prepared, namely 0.03%, 0.05%, 0.08%, 0.10%, and 0.12% BAC.

For each trial in the laboratory, Alcoscan strip readings were completed under identical incandescent lighting conditions. A single desk lamp using a standard 60 Watt bulb was placed approximately two feet from the laboratory table at which readings were taken.

Temperature Conditions

Data were collected under three different ambient temperature conditions, namely 5. C., 20. C., and 35. C. (41. F., 68. F. and 95. F.). The extreme temperatures were simulated in the laboratory by collecting all data while inside a standard walk-in environmental chamber.

A number of effects of extreme temperatures are possible. For instance, the rate at which the strip changes color in response to alcohol is expected to vary as a function of ambient temperature because the rate at which the enzyme reaction occurs is known to be temperature related. This may be of practical concern as the color change may be significantly slowed by low temperature conditions. Another possibility is that higher temperatures may cause some alcohol in a saliva sample to evaporate, thereby reducing the reading on the enzyme treated strips because there would be less alcohol present to which the enzyme could react. If this effect occurs, it could produce lower than expected readings.

Procedure

ALCOSCAN strips were brought in contact with alcohol-spiked saliva samples following procedures prescribed by the manufacturer. The provided saliva swab was fully saturated with the dosed saliva sample by pressing the foam pad against the side of the saliva container to ensure maximum absorption of the fluid by the sponge-like material. The saliva on the totally saturated swab was then transferred to the ALCOSCAN test strip. After five (5) seconds the test strip was blotted gently against the provided blotting paper for five (5) seconds, and then transferred immediately (within 3 seconds) to the foil envelope provided by the manufacturer. Each strip was read twice, i.e., at 5 minutes and at 10 minutes after the initial insertion in the foil envelope. Between readings, the Alcoscan strip was returned to the foil envelope for protection to minimize the risk of alcohol evaporation during the waiting periods. In each case, two experimenters independently estimated the BAC of the saliva sample to two digits (e.g. 0.10%) by comparing the color of the Alcoscan strip against the three standard colors provided by the manufacturer (set at 0.01%, 0.05%, and 0.10% BAC), and interpolating when the color appeared to fall between the standards.

Ten (10) trials under each BAC condition at each temperature were run. Each experimenter read each strip blind, without knowing how much alcohol the strip had been saturated with. The order in which different saliva-alcohol concentrations were presented was randomized.

Results

Mean BAC estimates based on readings of the Alcoscan strips five and ten minutes after they were saturated with spiked saliva samples are presented in Figures 1, 2, and 3. Figure 1 shows mean estimates at an ambient temperature of 5. C. (41. F.). Figures 2 and 3 show mean estimates at 20. C. and 35. C. respectively (i.e. 68. F. and 95. F.). In each case, the estimates of the two independent raters have been combined after it was determined that their concurrent ratings were highly correlated (r = 0.97) for both the five minute and the ten minute conditions. The bars in each figure represent the range of judgments made by the two raters for the ten strips tested at each BAC level, in both the five minute and ten minute conditions.

Regarding estimates made at the 5. C. (41. F.) ambient temperature, Figure 1 shows that BAC estimates made five minutes after the strips were saturated with alcohol consistently underestimated actual BACs. BAC estimates made ten minutes after the strips were saturated much more closely approximated the actual target BACs, supporting the notion that the rate of the enzymatic reaction is slowed down by the lower temperature. However, even under the ten minute condition, there is considerable variability in raters' BAC estimates at all test BACs.

Regarding BAC estimates made at room temperature (20. C. = 68. F.) and above (i.e. 35. C. = 95. F.), Figures 2 and 3 illustrate that it makes little difference whether readings are taken at five or ten minutes after strips are saturated with the alcohol sample. Time does not appear to be an important dimension at these temperatures, as it was at the lower temperature. BAC estimates markedly overestimate actual BACs in the mid-range (0.05-0.08% BAC), appear relatively accurate at 0.10% BAC and tend to underestimate at BACs above 0.10%. However, there is still a great deal of variability in raters' judgments at all the test BACs.

False Negatives and False Positives.

Accuracy can also be described in terms of the frequency with which BAC judgments are false positive or false negative.

In the context of this assessment, a false negative judgment occurs when a rater incorrectly judges a strip as showing a BAC 0.10% when, in fact, the BAC in question was . 0.10 %. False negatives are especially important when the device is being used by private citizens. When these false negative judgments occur, an individual would be more likely to incorrectly assume that it is legally safe to drive, thus increasing the probability of both arrest and accident.

A false positive judgment occurs when a rater incorrectly judges a strip as showing a BAC .0.10% when it is, in fact, 0.10%. False positive readings are especially troublesome when devices are being relied upon for law enforcement use and decisions regarding arrest for impaired driving are being made based on the results from such devices. A high false positive rate would mean that police would arrest a large number of individuals that would subsequently be released because of a lack of confirmation by an evidential breath tester.

The false negative and false positive rates found using the Alcoscan strips are summarized in Table 1.

False negatives appear to present the greatest problem at the low temperature condition (5. C.), whereas there are few false positives at this temperature level. However a sizeable percentage of false positives is evident at normal room temperature and above.

Discussion/Conclusion

In a highway safety context, the high variability in BAC estimates coupled with the high proportion of false positives suggest that this technology is not satisfactory as a screening device for law enforcement. Use by private individuals appears more promising, if the device is not used at low environmental temperatures. At room temperature and above, the chance is relatively low that the rating will falsely indicate that the individual is below the legal limit when in fact he is not. However, given the large variability in rating accuracy at all BAC levels, the utility of the device, even for private citizens, is subject to question.

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Table 1

Percentage of False Positive and False Negative Judgments Made Five and Ten Minutes after Alcohol Saturation Under Three Ambient Temperature Conditions (5°C., 20°C., and 35°C.).

At 5°C. (41° F.)

	False Positive	False Negative
5 Minutes After Alcohol Saturation	0 %	55%
10 Minutes After Alcohol Saturation	3 %	34%

At 20° C. (68° F.)

	False Positive	False Negative
5 Minutes After Alcohol Saturation	35 %	10 %
10 Minutes After Alcohol Saturation	53 %	0 %

At 35° C. (95° F.)

	False Positive	False Negative
5 Minutes After Alcohol Saturation	20 %	10 %
10 Minutes After Alcohol Saturation	33 %	5 %

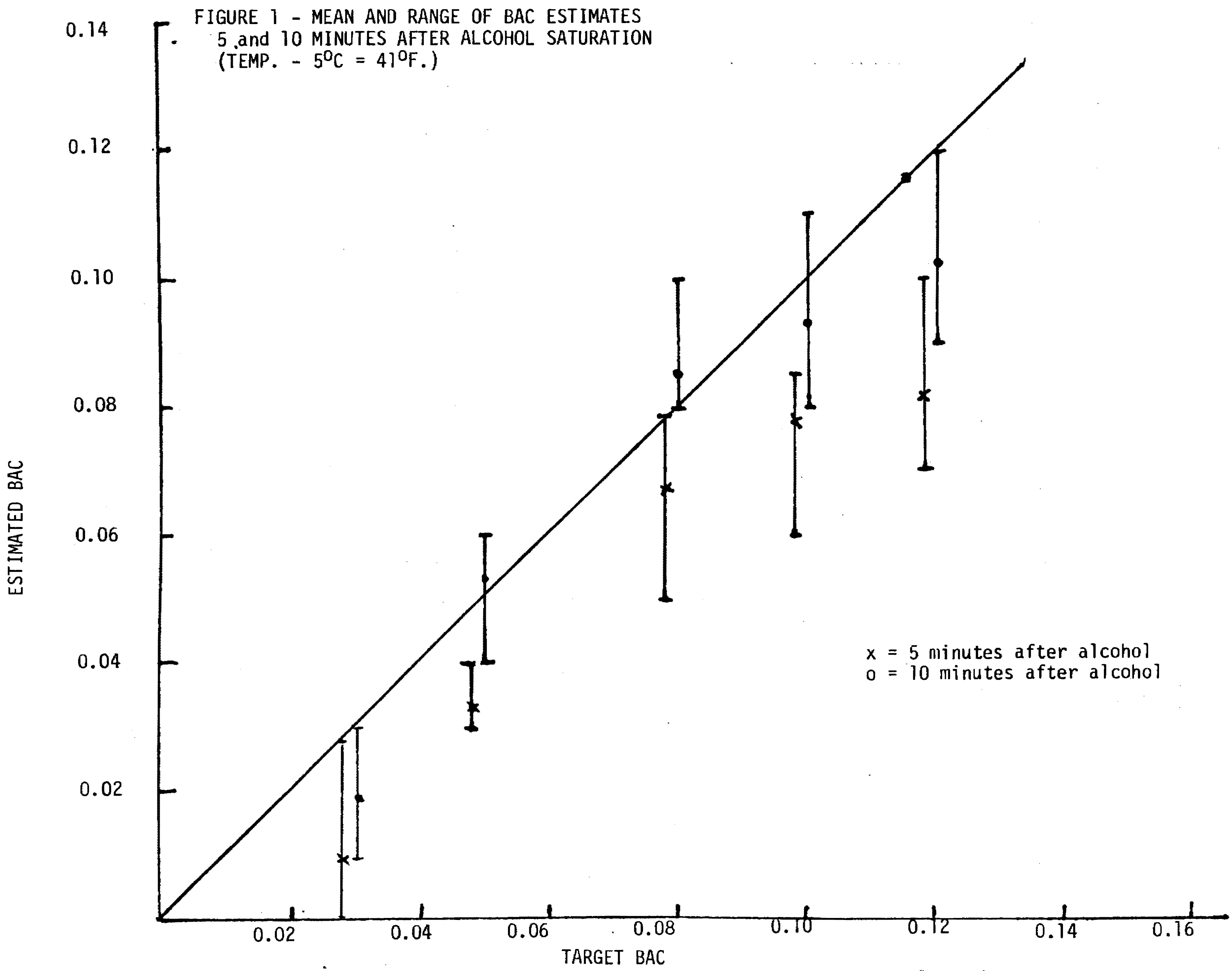

FIGURE 1 - MEAN AND RANGE OF BAC ESTIMATES 5 and 10 MINUTES AFTER ALCOHOL SATURATION (TEMP. - $5^{o}C = 41^{o}F$.)

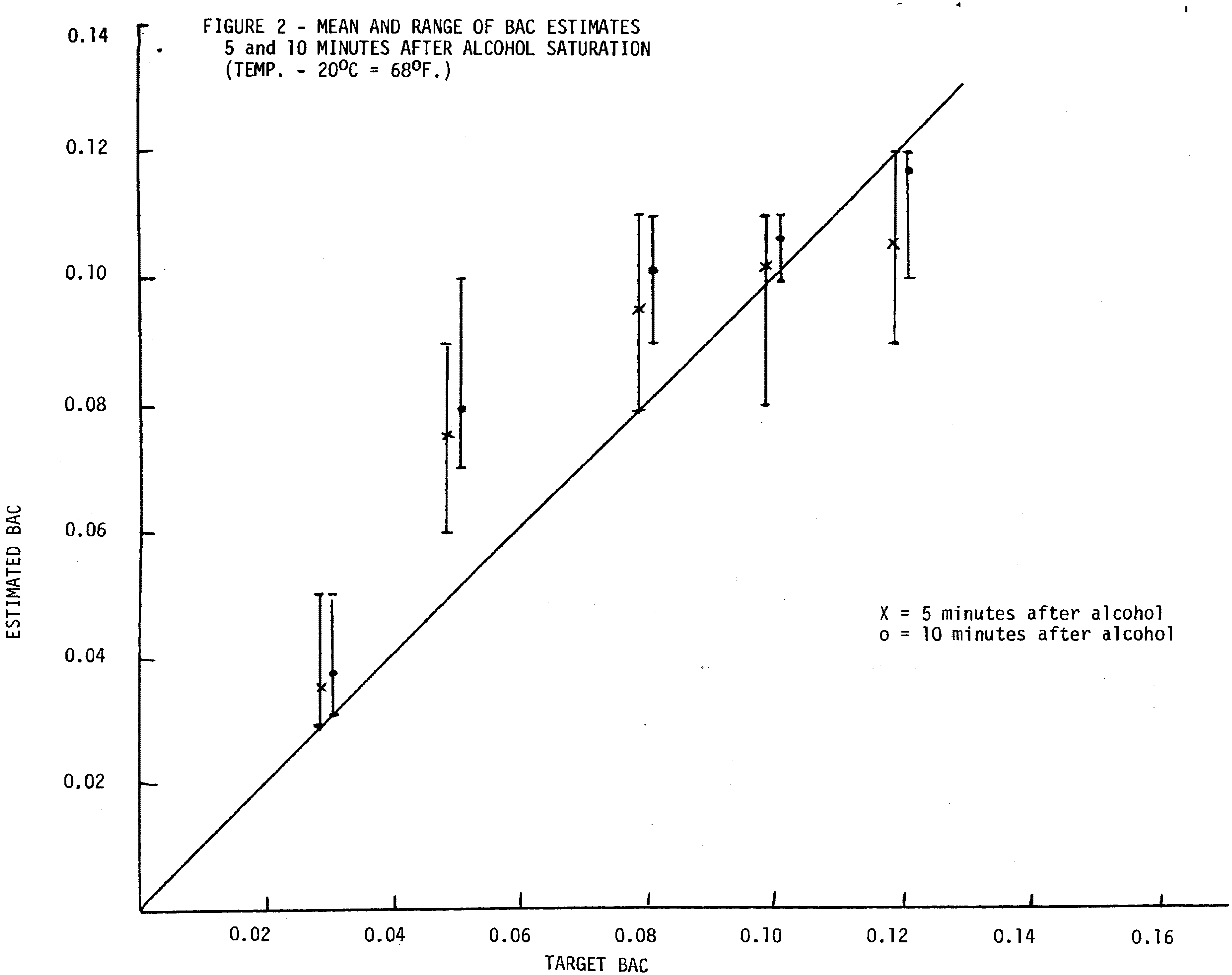
FIGURE 2 - MEAN AND RANGE OF BAC ESTIMATES
5 and 10 MINUTES AFTER ALCOHOL SATURATION
(TEMP. - 20°C = 68°F.)
ESTIMATED BAC
0.14
0.12
0.10
0.08
0.06
0.04
0.02
TARGET BAC
0.02
0.04
0.06
0.08
0.10
0.12
0.14
0.16
X = 5 minutes after alcohol
o = 10 minutes after alcohol

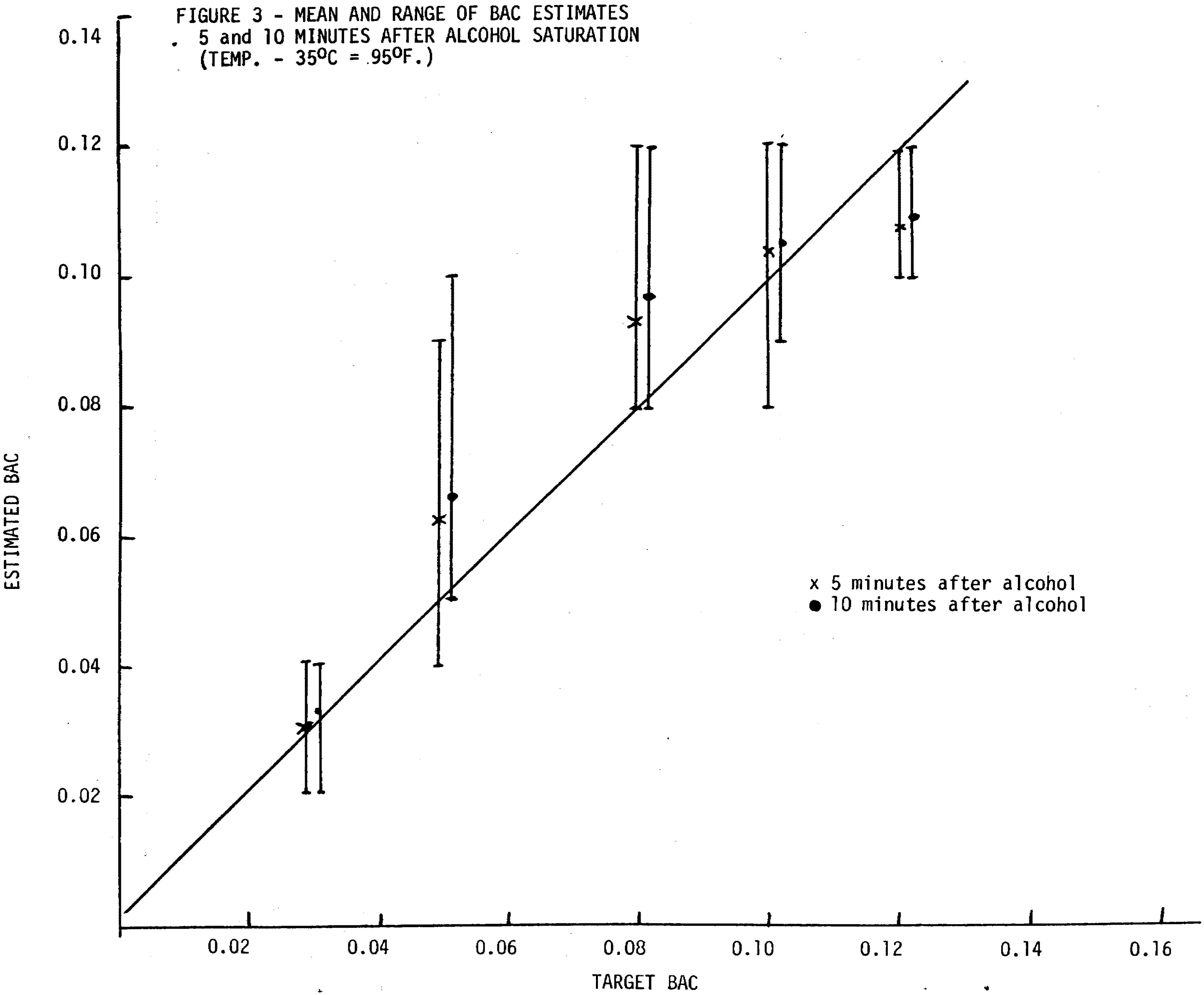
FIGURE 3 - MEAN AND RANGE OF BAC ESTIMATES
5 and 10 MINUTES AFTER ALCOHOL SATURATION
(TEMP. - 35°C = 95°F.)
ESTIMATED BAC
0.14
0.12
0.10
0.08
0.06
0.04
0.02
TARGET BAC
0.02
0.04
0.06
0.08
0.10
0.12
0.14
0.16
x 5 minutes after alcohol
● 10 minutes after alcohol