SDPD Forensic Chemistry Section Breath Alcohol Analysis - Uncertainty of Measurement of Ethanol in a Breath sample By Intoxilyzer 8000

### Introduction

The overall estimation of uncertainty of measurement was determined for five Intoxilyzer 8000 instruments. The process of alcohol quantitation using the Intoxilyzer 8000 instrument was evaluated to include the following four factors of uncertainty: instrument accuracy, GEBS accuracy, precision, and measured accuracy.

## Procedure

Twenty replicates of five GEBS values: 0.040 g/210L, 0.080 g/210L, 0.100 g/210L, 0.200 g/210L, and 0.400 g/210L were run on each instrument to determine the precision and measured accuracy at each GEBS level. The replicates were performed by three different analysts. The replicates were obtained between 4/7/2017 and 6/5/2017. The four factors of uncertainty were determined for each GEBS value and used in combined standard uncertainty and expanded uncertainty calculations for each GEBS value. (see calculation sheets)

### Instruments

Serial #'s: 80-000715, 80-000728, 80-000717, 80-000718, and 80-006056.

# **GEBS** Tanks

Value	Lot #'s	Expiration date
0.040g/210L	12716040A8	6-5-2018
0.080g/210L	12415080A5	6-5-2017
0.080g/210L	03417080A2	3-5-2019
0.100g/210L	28515100A1	11-5-2017
0.100g/210L	23016100A1	9-5-2018
0.200g/210L	26615200A1	10-5-2017
0.400g/210L	24316400A4	10-5-2018

### **Defining Factors of Uncertainty of Measurement**

In estimating measurement uncertainty, the following factors that affect the measurement taken will be addressed:

### • <u>Reported Accuracy for the Intoxilyzer 8000:</u>

CMI Inc. reports the instruments accuracy at +/- 3% or +/- 0.003 g/210L whichever is higher. Below are the instrument accuracy values for each GEBS value used

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- 1. 0.040 g/210L Standard (+/- 0.003 g/210L)
- 2. 0.080 g/210L Standard (+/- 0.003 g/210L)
- 3. 0.100 g/210L Standard (+/- 0.003 g/210L)
- 4. 0.200 g/210L Standard (+/- 0.006 g/210L)
- 5. 0.400 g/210L Standard (+/- 0.012 g/210L)
  - **<u>Type B:</u>** This factor was determined to be a type B factor with a rectangular distribution because it is obtained from an outside source and no confidence interval was given. The standard uncertainty was calculated by dividing the accuracy value by the square root of three.

#### **Standard Uncertainty:**

- o 0.040 g/210L Standard (0.0017)
- o 0.080 g/210L Standard (0.0017)
- o 0.100 g/210L Standard (0.0017)
- o 0.200 g/210L Standard (0.0034)
- o 0.400 g/210L Standard (0.0069)

#### • Reported Accuracy of Gaseous Ethanol Breath Standard (GEBS):

The standards are composed of ethanol and nitrogen and come with a certificate of analysis from ILMO specialty gases. ILMO is an ISO/IEC 17025:2005 accredited laboratory. The reported accuracy of each standard is +/- 0.002 or 2% of the BAC, whichever is greater. This is an expanded uncertainty at a 95% confidence interval with a coverage factor of k=2. Five different levels of ethanol were analyzed. Below are the accuracy values that were divided by two to take into account the coverage factor.

- 1. 0.040 g/210L Standard ( $\pm 0.002 \text{ g}/210\text{L}$ ) / 2 = (0.001)
- 2. 0.080 g/210L Standard ( $\pm$  0.002 g/210L) / 2 = (0.001)
- 3. 0.100 g/210L Standard ( $\pm$  0.002 g/210L) / 2 = (0.001)
- 4. 0.200 g/210L Standard ( $\pm$  0.004 g/210L) / 2 = (0.002)
- 5. 0.400 g/210L Standard ( $\pm$  0.008 g/210L) / 2 = (0.004)
  - <u>**Type A:**</u> This factor is type A because it is experimental data evaluated by statistical analysis of a series of observations. This is known because the manufacture reports a confidence interval. The standard uncertainty was determined using a normal distribution and is reported using the straight value.

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### • Measured Accuracy:

The closeness of the average measurement to the accepted value represents the measured accuracy. The average difference of each of the five GEBS standard levels was calculated.

- 1. 0.040 g/210L Standard (0.001)
- 2. 0.080 g/210L Standard (0.001)
- 3. 0.100 g/210L Standard (0.001)
- 4. 0.200 g/210L Standard (0.005)
- 5. 0.400 g/210L Standard (0.004)
  - **<u>Type A</u>**: This factor is type A because it is experimental data evaluated by statistical analysis of a series of observations. The standard uncertainty was determined using a normal distribution and is reported using the straight value.

### • <u>Precision:</u>

The closeness of agreement between measured quantity values obtained by replicate measurements on the same or similar conditions represents the precision of the instruments. The standard deviation of the five standards were determined.

- 1. 0.040 g/210L Standard (0.0019)
- 2. 0.080 g/210L Standard (0.0014)
- 3. 0.100 g/210L Standard (0.0015)
- 4. 0.200 g/210L Standard (0.0019)
- 5. 0.400 g/210L Standard (0.0047)

• **<u>Type A:</u>** This factor is type A because it is experimental data evaluated by statistical analysis of a series of observations. The standard uncertainty was determined using a normal distribution and is reported using the straight value.

### Results

The reported uncertainty of measurement will be the same for all five instruments. For the Intoxilyzer 8000 instruments listed above, the expanded uncertainty will be reported as  $\pm -0.006$  g/210L at a confidence level of approximately 95% (k=2) for breath results below 0.100 g/210L, and as  $\pm -7\%$  at a confidence level of approximately 95% (k=2) for breath results between 0.100-0.400 g/210L. The overall uncertainty of measurement will be applied to the average of the two

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breath samples that agree within 0.02 g/210L for levels that are 0.400 g/210L or below. Levels that are greater than 0.400 g/210L will not have an established uncertainty and should be considered to have a value greater than 0.400 g/210 L.

Each instrument is capable of measuring a known GEBS value  $\pm -0.010$  grams % of the true value for values ranging between 0.08 to 0.30 grams %, and each successful breath test will be comprised of two separate breath samples which do not differ from each other by more than 0.02 g/ 210L as per Title 17.

### **Reevaluating Uncertainty of Measurement**

This write up updates the current uncertainty of measurement budget table to account for the instruments accuracy and GEBS accuracy over a range of alcohol levels.

After 6/21/2017, any instrument that is placed in use for case work shall initially have the above procedure run on it. If the expanded uncertainty values do not exceed the current reported uncertainty of measurement the instrument will be placed in use with the current uncertainty calculation. If the instruments expanded uncertainty values exceed the current reported uncertainty of measurement the overall uncertainty of measurement will be reestablished or that instrument will be placed out of use for case work.

QA will be performed yearly on each instrument. The data obtained will be evaluated to determine if the instrument is still within the reported uncertainty of measurement. If it is deemed that an instrument is not within the reported uncertainty, the instrument will be placed out of use or the overall uncertainty will be reestablished.

Technical Review	Date	6/5/0
Administrative Review_ SunM	Date	6/20/17
Quality Assurance Manager Min	Date	7/17/17