State of California—Health and Human Services Agency
California Department of Public Health

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January 20, 2021

TO: Participants in the December 2020 Voluntary Proficiency Test in Forensic Alcohol Analysis

SUBJECT: Assigned Values and Expected Ranges of Results for the December 2020 Proficiency Test in Forensic Alcohol Analysis

Enclosed is a summary of the descriptive statistics for the Department's December 2020 voluntary proficiency test in forensic alcohol analysis. The Department prepared four blood-alcohol pools (11030A, 11030B, 11100A, and 11100B) for this proficiency test. Included in the summary are the target formulation values for the pools, the test pools' true values as determined by the Department's analyses, the peer-group or consensus values and the standard deviations, general descriptive statistics, and graphical summaries of the distribution of participant results. A total of 19 laboratories elected to voluntarily participate in this proficiency test, with 17 laboratories submitting test results within the time limit.

With the 2017 revisions to the Title 17 regulations, the Department is no longer authorized to evaluate participants' performances on proficiency tests. Instead, staff of each individual laboratory must evaluate the laboratory's results to determine whether they are consistent with expected test results [17 CCR §1220.1 (b)]. The comments below describing the procedures historically used by the Department when evaluating test results are advisory in nature and intended to assist the laboratory staff in evaluating their own results.

Historically, the Department has determined the acceptable limits of performance based on reported results that are within the range representing ±5% of the 99% confidence interval of the peer group mean, where the range has been truncated to two significant figures (Table 1). This range was described as the "Tier #2 interval." The Department also calculated a narrower, "Tier #1 interval," which represents the range of reported results that are within ±5% of the 95% confidence interval of the peer group mean, where the range is based on the results reported to three significant figures (Table 1). Tier #1 was expected to include those laboratories demonstrating a high degree of accuracy. The second, wider tier was intended to include those laboratories not as close to the central tendency as required by the first tier, but still accurate and therefore adequately competent.

One of the recent revisions to the Title 17 regulations was to permit the expression of results to either two or three decimal places. When reporting results to the second decimal place, the digit in the third decimal place must be deleted [17 CCR §1220.4 (b)]. The regulations are silent with respect to the procedures for determining the third decimal place.

The majority of participants [12 out of 17] reported results to three decimal places. Under these circumstances, the wider second tier based on two decimal place results, which again historically was used by the Department to evaluate the laboratories' results, is no longer appropriate. The Tier #1 intervals are shown on the report forms.

The IUPAC[1] International Harmonized Protocol for the Proficiency Testing of Analytical Chemistry Laboratories (Harmonized Protocol) recommends the use of z-scores for evaluating proficiency test data.

Z-score calculation formula:

$$z = \frac{\mathbf{X} - \mathbf{X}_a}{\sigma_p}$$

where: $\mathbf{X}$ is a participant result, $\mathbf{X}_a$ is a consensus value, and $\boldsymbol{\sigma}_p$ is the fitness-for-purpose standard deviation, see also Table 2,

However, the Harmonized Protocol notes that that the interpretation of the z-scores is based on the normal distribution of reported results, in which case the z-scores can be expected to follow the standard normal distribution. As indicated in Table 2, some of the results in this proficiency test were found to be not normally distributed. Accordingly, the use of z-scores may not be completely appropriate, but they still may be useful to identify outlier and/or warning level results. The expression for calculating a z-score is included in Table 2. Generally a score between -2 and +2 ($|z| \leq 2$) is considered satisfactory or acceptable. A score outside the range -3 to +3, inclusive ($|z| \geq 3$) is considered unsatisfactory or unacceptable and the laboratory must take corrective actions. Z-scores between -3 and -2 or +2 and +3 ($2 < |z| < 3$) are considered questionable and these two ranges should be used as warning limits. Scores within the warning limit ranges in two or more consecutive test events could be considered unacceptable.

The proficiency test results expressed as *z*-scores for the participants whose results were used to determine the peer group mean and statistics in the December 2020 test are summarized in Figure 7[2]. Participants are identified by codes. An enclosure with the current correspondence provides codes for the results submitted by your laboratory.

Another approach for evaluating proficiency test data, which is non-parametric and does not require the data to be converted to a standard normal form, divides the test data at regular intervals or quantiles[3]. The quartile is a type of quantile: the first quartile (Q_1) is defined as the middle number between the lowest number and the median of the data set. The second quartile (Q_2) is the median of the data set. The third quartile (Q_3) is the middle number between the median and the highest number of the data set[4]. The interquartile range (IQR), a measure of the dispersion of the data, is the difference between the upper and lower quartiles ($IQR = Q_3 - Q_1$) and represents 50% of the data range. Boundaries (called fences) are set at $Q_1 - 1.5$ IQR

[1] International Union of Pure and Applied Chemistry (IUPAC)
[2] When calculating z-scores, the Department used the round even mean of the three decimal place duplicate results reported by the participants since this represents the best estimate of the sample concentration.
[3] See Statistics and Chemometrics for Analytical Chemistry Sixth Edition, Miller and Miller (p. 158)
[4] There are two ways to calculate quartiles (generally, percentiles): Standard and Cleveland methods. The Department used the Standard method.

(lower fence) and Q_3 + 1.5 IQR (upper fence) to identify potential outliers in the tails of the distribution.

In Figure 5, the quartile data from pools 11030A and 11030B are presented as box and whisker or Tukey plots with the quartiles and fences shown. The IQR is represented as the box. The median of the data is shown by a black line and the mean of the data is shown by a red line inside the box. Lines (“whiskers”) are drawn at 10% (lower) and 90% (upper) of the data range. Figure 6, presents the same data for pools 11100A and 11100B. These figures can be used by the participants to evaluate their data.

A copy of this report is available on Food and Drug Laboratory webpage.

Sincerely,

Clay Larson, Chief
Abused Substances Analysis Section
Food and Drug Laboratory Branch

For questions or additional information, contact the Food and Drug Laboratory Branch:

Phone – (510) 412-6220

Web - https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FALP.aspx

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Statistical Data for December 2020 Proficiency Test in Forensic Alcohol Analysis

Table 1 CDPH Tier #1 and Tier #2 Acceptable Ranges (grams%)

Pool #	Pool Date Code	Peer Group Mean	Tier #1	Tier #2
#1A	11030A	0.083	0.076 – 0.090	0.07 – 0.09
#1B	11030B	0.161	0.150– 0.172	0.14 – 0.17
#2A	11100A	0.132	0.123 – 0.141	0.12 – 0.14
#2B	11100B	0.230	0.216 – 0.244	0.21– 0.24

Table 2 Summary of Test Pool Data

Parameter		Pool1A (11030A)	Pool 1B (11030B)	Pool 2A (11100A)	Pool 2B (11100B)
Pre-distribution Data	Target Value	0.08	0.16	0.13	0.23
	True Value[5]	0.083	0.160	0.132	0.228
	Standard Deviation	0.0006	0.0007	0.0007	0.0014
Descriptive statistics	Mean	0.083	0.161	0.132	0.230
	Adjusted Mean[6]	0.083	0.161	0.132	0.230
	Standard Error[7]	0.0003	0.0007	0.0005	0.0005
	Median	0.083	0.161	0.132	0.230
	Standard Deviation	0.0015	0.0033	0.0032	0.0022
	Minimum	0.080	0.156	0.129	0.226
	Maximum	0.086	0.172	0.144	0.236
	Count	22[8]	22[8]	22[8]	22[8]
Non-parametric statistics (SigmaPlot)	Q1 (25%)	0.082	0.160	0.130	0.229
	Q3 (75%)	0.084	0.162	0.133	0.231
	IQR	0.002	0.002	0.003	0.002
	Lower Fence	0.079	0.157	0.126	0.226
	Upper Fence	0.087	0.165	0.138	0.234
Histogram		Figure 1	Figure 2	Figure 3	Figure 4
Normal distribution?[9]		YES ($p=0.11$)	No ($p=0.006$)	No ($p<0.001$)	YES ($p=0.086$)
Box Plot/Kernel Density Plot (python)		Figure 5	Figure 5	Figure 6	Figure 6
Robust mean, X*[10]		0.0830	0.1610	0.1316	0.2300
Robust standard deviation, σ_{rob}		0.0015	0.0018	0.0022	0.0016
Fitness-for-purpose standard deviation, σ_p[11]		0.0024	0.0042	0.0036	0.0057
Consensus value (X_a) - determined as Mode ($\mu_{1/2}$) of Gaussian Kernel distribution		0.0829	0.1609	0.1319	0.2298
Uncertainty of the consensus value, X_a, S.E.[12]		0.00084	0.00082	0.00099	0.00037
X_a ± S.E.		0.0829 ± 0.0008	0.1609 ± 0.0008	0.1319± 0.0010	0.2298 ± 0.0004
z-score		$z = \frac{X - X_a}{\sigma_p}$	$z = \frac{X - X_a}{\sigma_p}$	$z = \frac{X - X_a}{\sigma_p}$	$z = \frac{X - X_a}{\sigma_p}$

[5] Based on CDPH's Headspace Gas Chromatographic Method
[6] Mean determined from participant data after the removal of outlier(s) using MAD method (https://www.itl.nist.gov/div898/handbook/eda/section3/eda35h.htm)
[7] Standard Error of the Mean
[8] A total of 22 laboratories participated and analyzed a total of 35 sample sets.
[9] Shapiro-Wilk test used at 0.05 significance level (i.e., P-value greater than 0.05).
[10] Robust mean of the results reported by the participants was calculated using Algorithm A in Annex C of ISO 13528:2005.
[11] The Department has determined a value for σ_p as 2.5% of robust mean for roughly symmetrical distributions based on the uncertainties associated with the reported results on recent tests together with the 5% accuracy and precision standard of performance requirements set forth in the regulations. In case of skewed, non-normal distributions, the revised, derived Horwitz equation (σ_p') is used : $\boldsymbol{\sigma_p' = 0.02 * \mu_{1/2}^{0.8495}}$
[12] Derived from bootstrep procedure with bandwidth (h) equal $0.75 * \sigma_p$

Figure 1

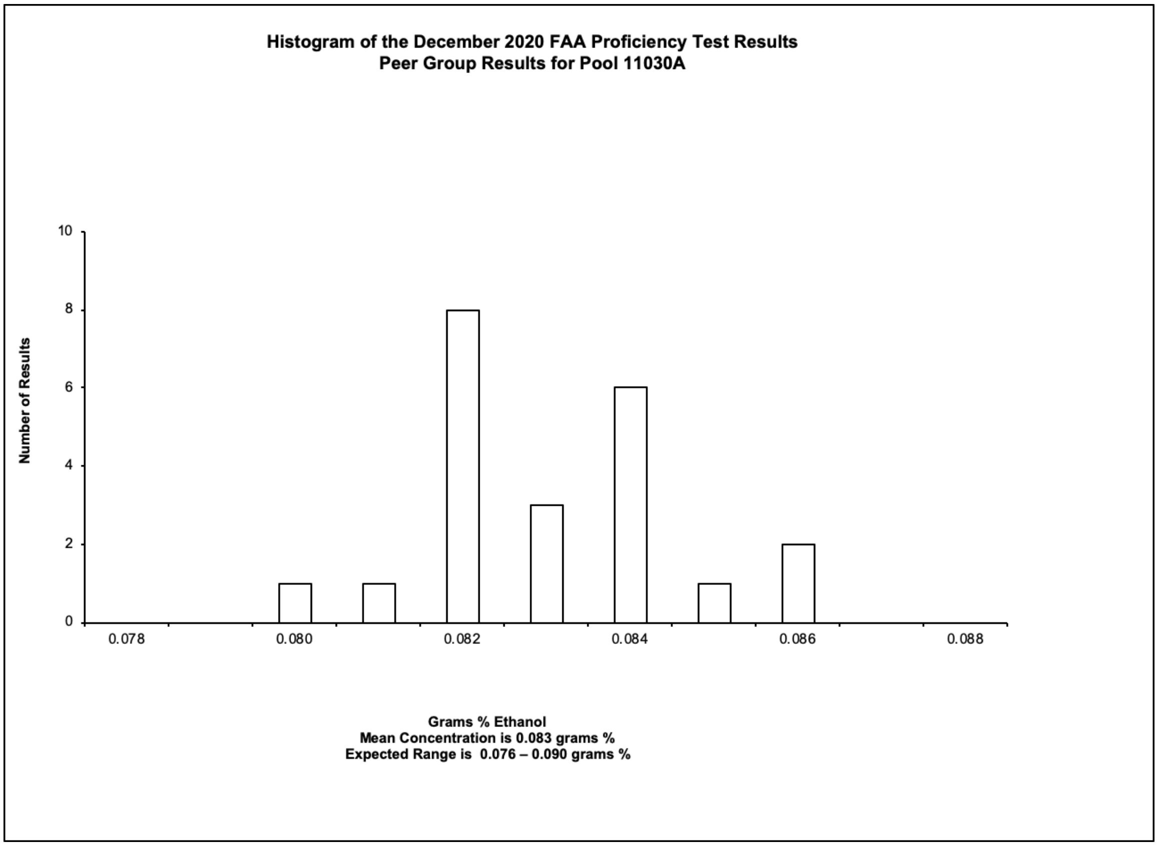


Figure 2

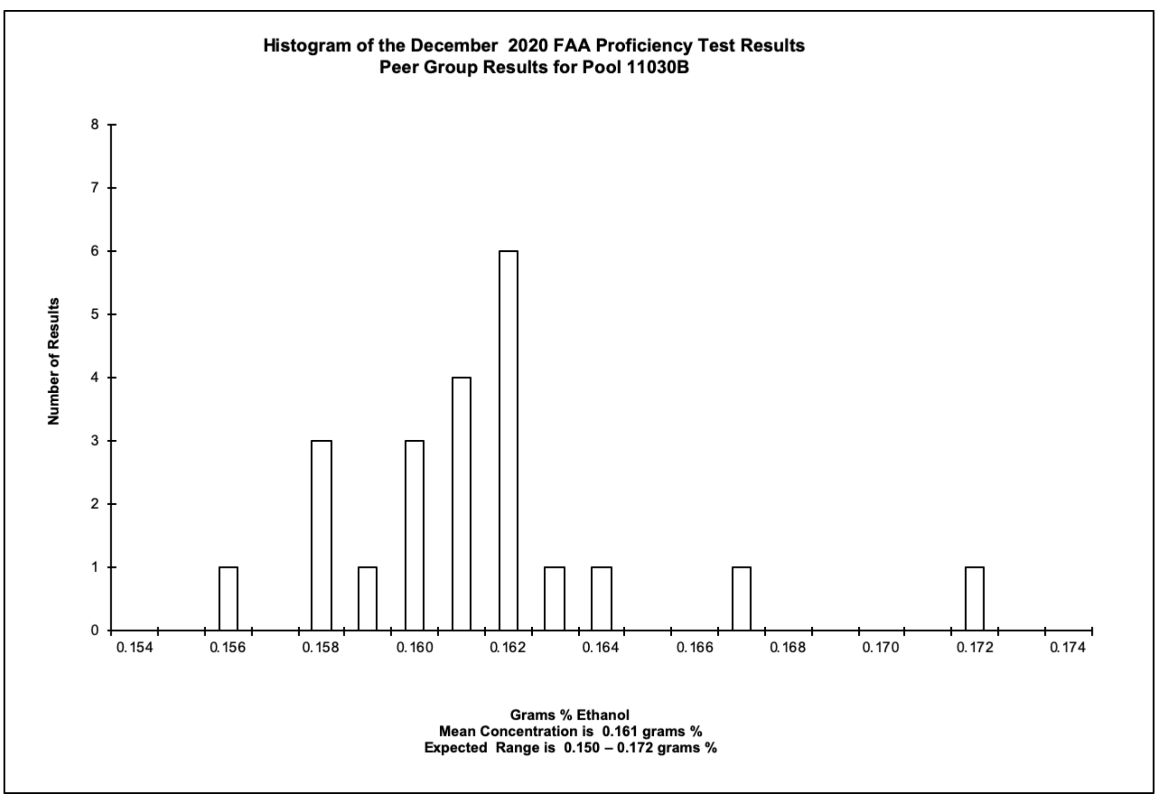


Figure 3

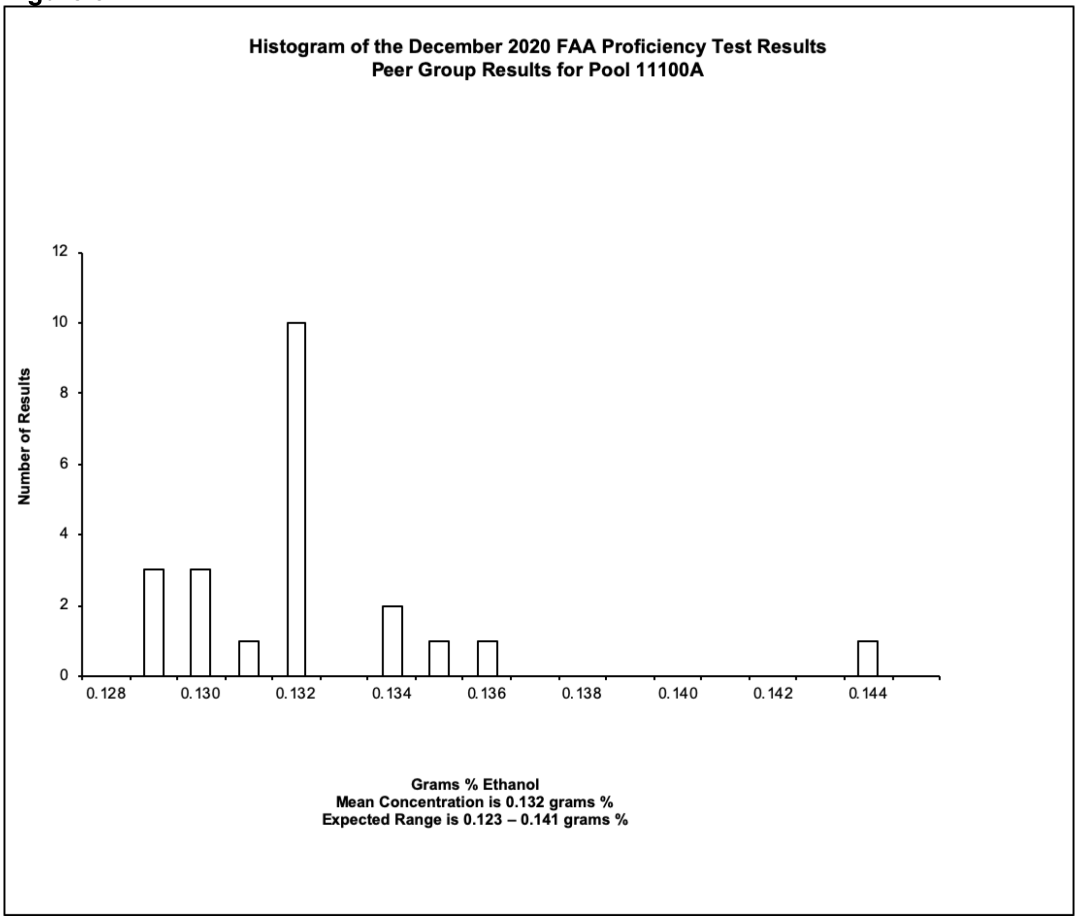


Figure 4

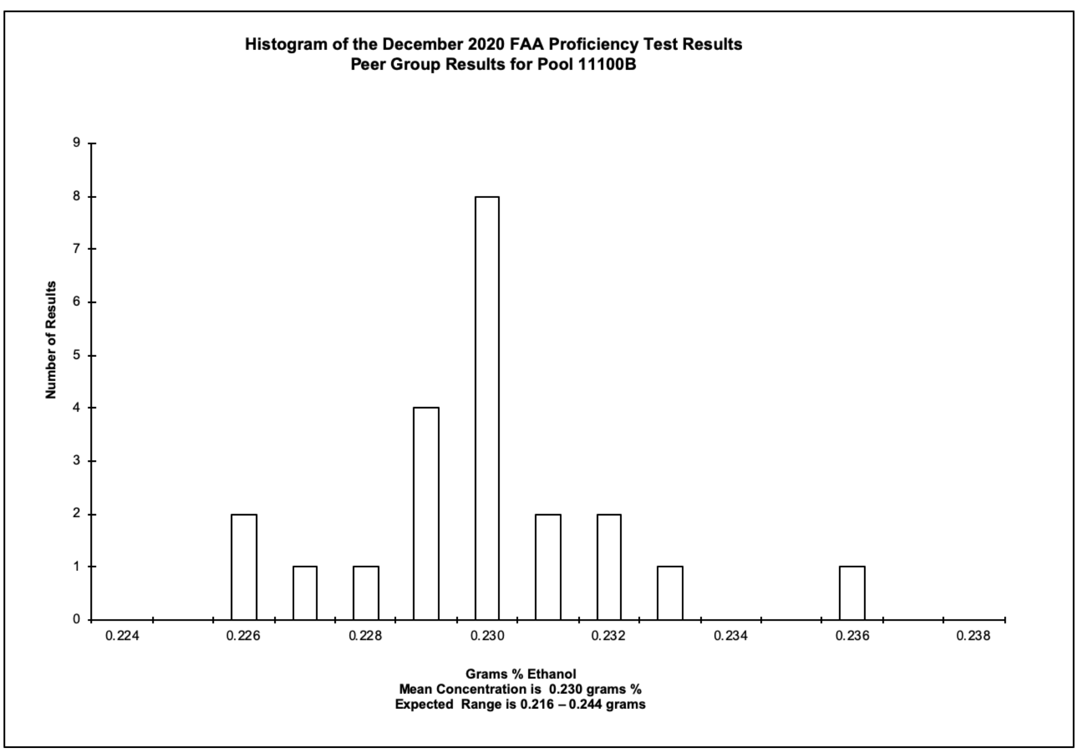
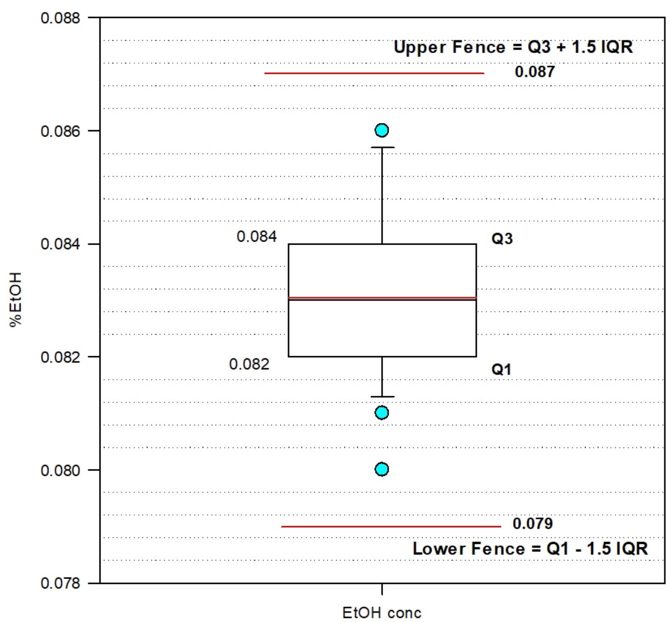
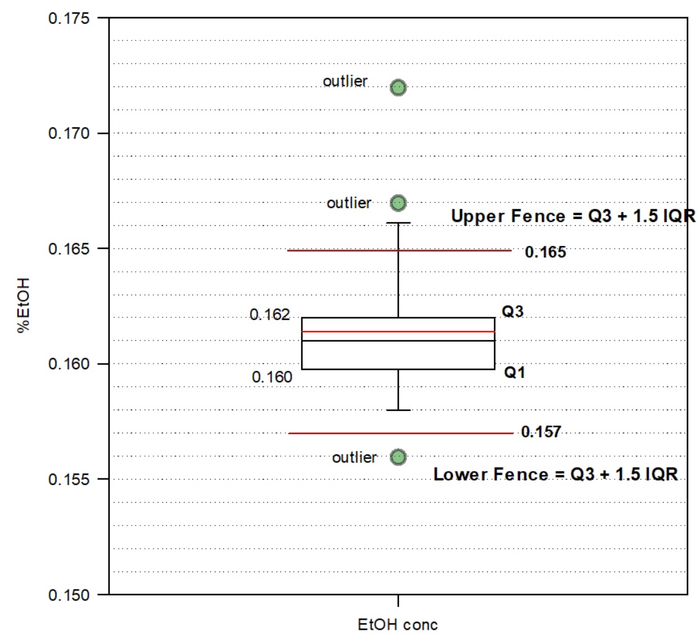


Figure 5 – SigmaPlot Analysis of Pools 11030A & 11030B (Pools 1A & 1B)

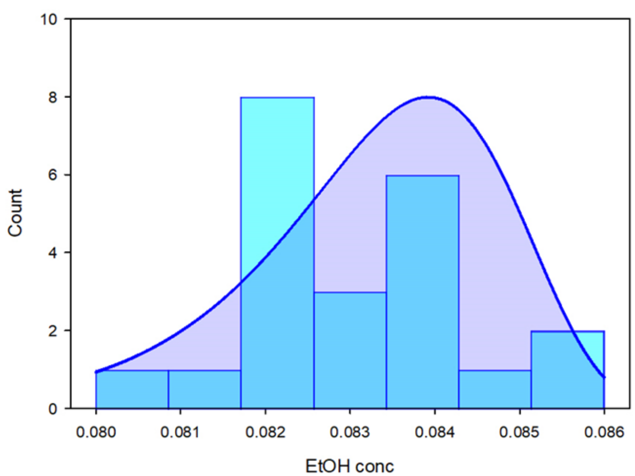
Box Plot 11030A



Box Plot 11030B



Histogram 11030A



Histogram 11030B

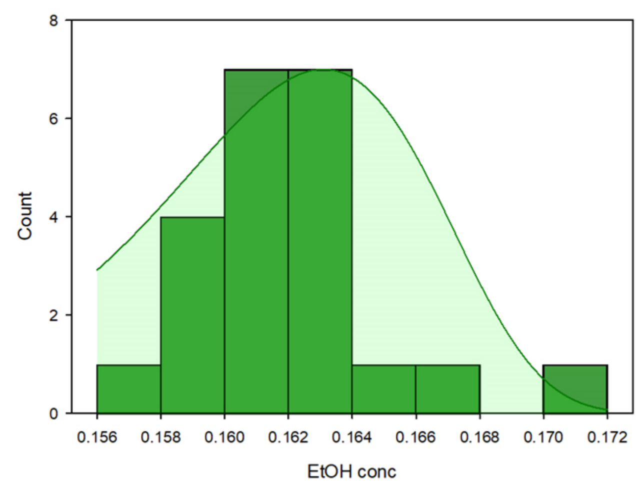
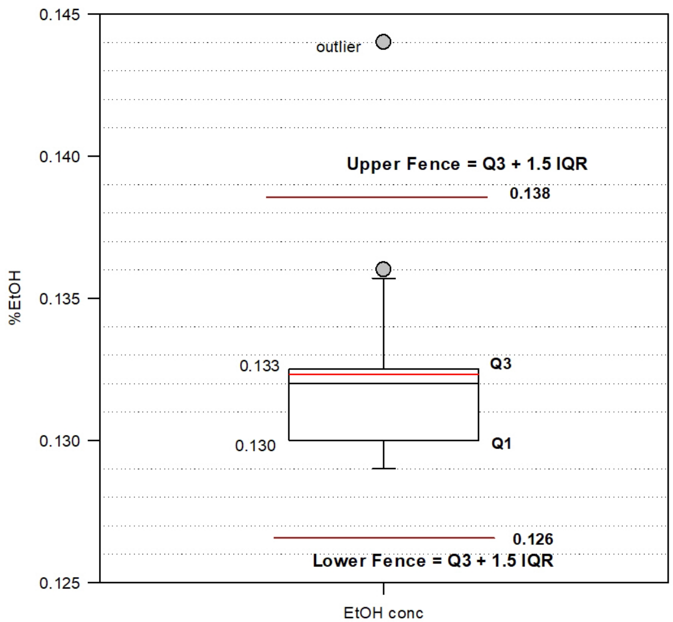
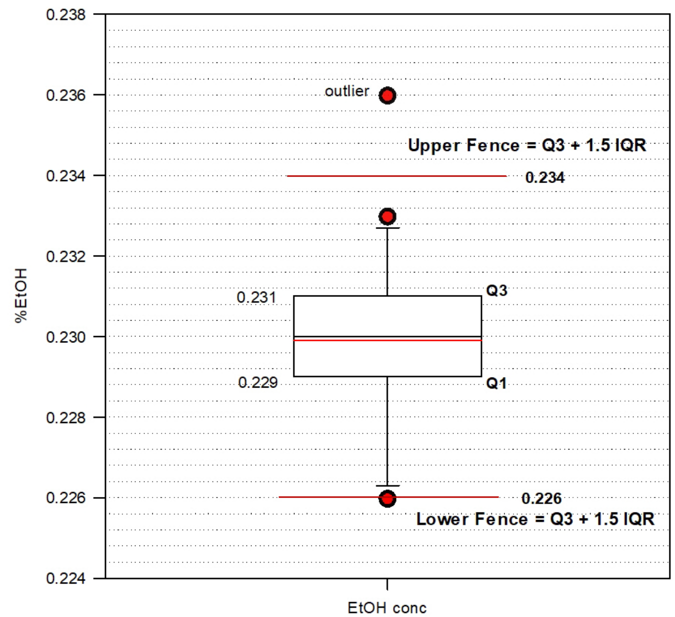


Figure 6 – SigmaPlot analysis of Pools 11100A & 11100B (Pools 2A & 2B)

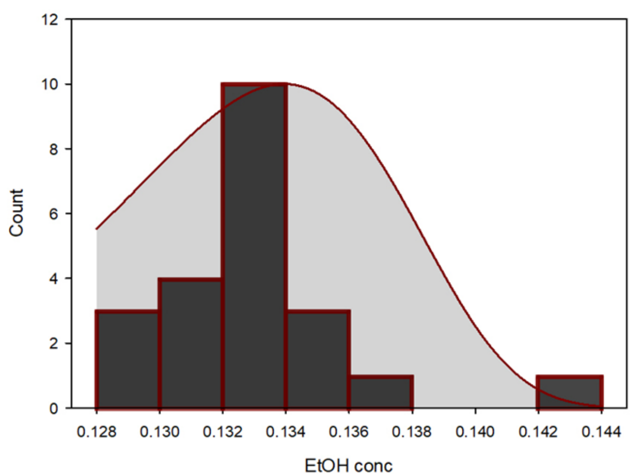
Box Plot 11100A



Box Plot 11100B



Histogram 11100A



Histogram 11100B

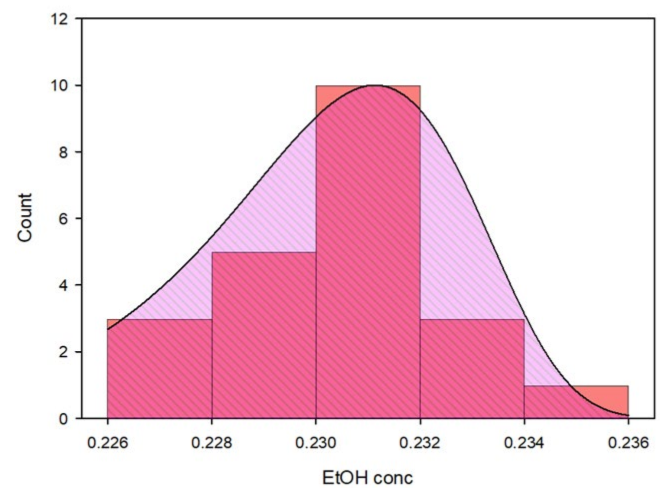
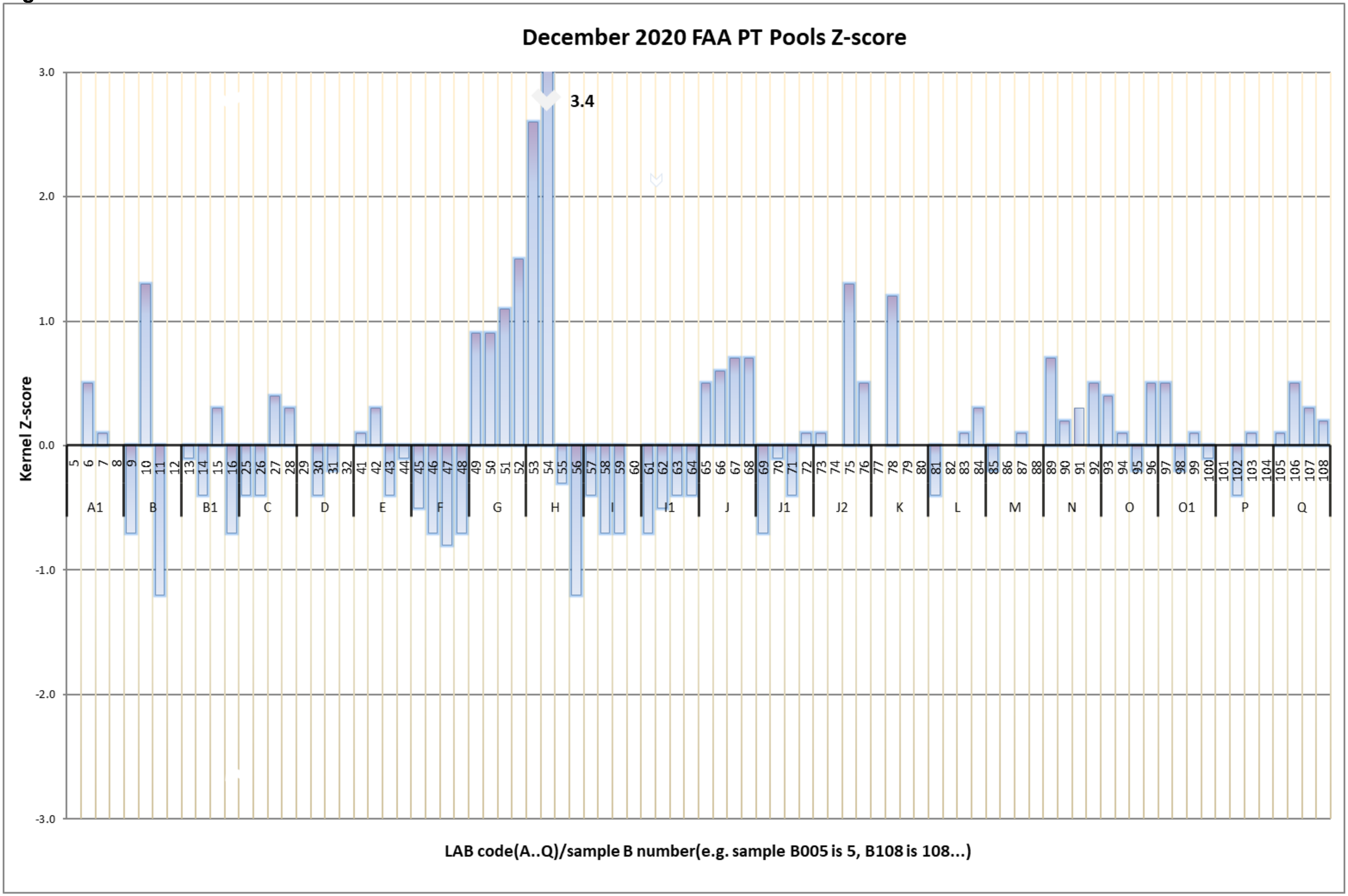


Figure 7


December 2020 FAA PT Pools Z-score
Kernel Z-score
3.4
LAB code(A..Q)/sample B number(e.g. sample B005 is 5, B108 is 108...)
A1
B
B1
C
D
E
F
G
H
I
I1
J
J1
J2
K
L
M
N
O
O1
P
Q