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

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To: Contact Person at a Forensic Alcohol Laboratory

Health and Safety Code Section 100702 (b) requires forensic alcohol analysis laboratories to participate annually in an external proficiency test in alcohol analysis, where the test samples are obtained from an approved proficiency test provider. The two approved proficiency test providers are: Collaborative Testing Services (CTS), Sterling, VA and the American Association for Clinical Chemistry/College of American Pathologists (AACC/CAP), Northfield, IL[1]. California laboratories' results are reported directly to the Department by the test providers [17 CCR §1216.1 (a)(2)].

Last year, your laboratory participated in an external proficiency test. I have enclosed a summary of the individual results for your laboratory as reported to the Department by the provider(s). The reported results are expressed to four decimal places (CTS Results) or three decimal places (AACC/CAP Results). I have also enclosed a report summarizing the results obtained by all California laboratories on the external proficiency tests. The summary report shows the California laboratory peer group means. Also, to assist you in the evaluation of your results, the summary report includes Tier #1 and Tier #2 ranges of acceptable results that are based on the standard of performance requirements set forth in Section 1220.1 (a)(1) of the Title 17 regulations. Tier #1 represents the range of reported results that are within ±5% or 0.005 grams% (whichever is greater) of the 95% confidence interval of the peer group mean. Tier #2 represents the range of reported results that are within ±5% or 0.005 grams% (whichever is greater) of the 99% confidence interval of the peer group mean where the range has been truncated to two significant figures. Tier #1 is expected to include those laboratories demonstrating a high degree of accuracy. The second, wider tier would include those laboratories not as close to the central tendency as the laboratories in the first tier, but still accurate and therefore adequately competent. Historically, the Department used the truncated Tier #2 ranges when evaluating a laboratory's results.

The results reported by California laboratories have also been converted to z-scores. This is accomplished by dividing the difference in a reported result from the consensus group mean value by an estimate of the fitness-for-purpose standard deviation.

[1] The California Health and Safety Code (§100702) requires forensic alcohol laboratories to participate annually in an external proficiency test for alcohol analysis using proficiency test samples "obtained from any ASCLD/LAB approved test provider". In 2016, ASCLD/LAB "merged" with the ANSI-ASQ National Accreditation Board (ANAB) and it appears that the accreditation organization "ASCLD/LAB" no longer has a public presence. ANAB approves proficiency test providers based on the providers' accreditation under the ISO 17043 standards. The ANAB website (www.anab.org), lists two providers of alcohol proficiency test samples, Collaborative Testing Services (CTS), Sterling, VA and the American Association for Clinical Chemistry/College of American Pathologists (AACC/CAP)

The conversion of results to z-scores utilizing fitness-for-purpose standard deviation makes all proficiency test results directly comparable regardless of concentration. It also allows the review of the results obtained by a given laboratory over time & the multiple rounds of proficiency testing. A laboratory's performance can be evaluated using a *z*-score. Generally, a score between -2 and +2, inclusive ($|z| \leq 2$) can be considered satisfactory or acceptable. A *z*-score outside the range -3 to +3, inclusive ($|z| \geq 3$) should be considered unsatisfactory or unacceptable and the laboratory should 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.

The proficiency test results for California laboratory participants in the CTS (22-5641 and 22-5642) and the American AACC/CAP (2022, AL1, A – C) blood alcohol proficiency tests expressed as *z*-scores are summarized in Tables 1, 2, 3, and corresponding Figures 1, 2, and 3.

Tabular summaries of the proficiency test results for California laboratory participants in the CTS Breath Alcohol Simulator Solution Analysis (22-5681) and the CTS Breath Alcohol Calibration Verification test (22-5691) are included in Tables 4 and 5. See Figure 4 for visual presentation of z-scores for the 22-5691 test.

For the CTS proficiency tests, laboratories are identified by their Web codes assigned by the provider. For participants in the AACC/CAP proficiency tests, individual laboratory codes are included in the summary of individual results reported to the Department by AACC/CAP.

The Title 17 regulations require responsible staff of each laboratory to evaluate the ability of the laboratory's methods to meet the standards of performance set forth under Section 1220.1 (a)(1) of the Title 17 regulations [17 CCR §1220.1 (b)]. In addition, the laboratory staff are required to provide the Department with any documentation pertaining to corrective actions with respect to proficiency tests [17 CCR §1216.1 (a)(2)]. The attached report of the performances of California laboratories is intended to assist laboratory staff in evaluating the performances of their laboratories.

Thank you for your cooperation in maintaining reliable forensic alcohol analysis in the State.

Sincerely,

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

Enclosures:
Laboratory proficiency test results reported to the Department
California Laboratories External Proficiency Test Report

Results of California Laboratories on External Proficiency Tests for Alcohol Analyses 2022

Collaborative Testing Services Blood Alcohol Test No. 22-5641

California Labs	Item 1	Item 2	Item 3	Item 4
Mean	0.213	0.073	0.267	0.130
No. Participants	41	41	40[1]	41
Tier #1 Limits[2]	0.200 - 0.226	0.067 – 0.080	0.251 – 0.283	0.121 – 0.139
Tier #2 Limits[2]	0.19 - 0.22	0.06 - 0.08	0.24 – 0.28	0.11 - 0.13

[1] One laboratory's raw result submitted for Item 3 was excluded because it did not correspond to the laboratory's reported results and was likely due to a transcription error.

Collaborative Testing Services Blood Alcohol Test No. 22-5642

California Labs	Item 1	Item 2	Item 3	Item 4
Mean	0.072	0.282	0.141	0.177
No. Participants	23	23	23	23
Tier #1 Limits[2]	0.066 - 0.079	0.265 - 0.299	0.132 - 0.150	0.166 - 0.188
Tier #2 Limits[2]	0.06 – 0.08	0.26 – 0.30	0.13 – 0.15	0.16 – 0.19

[2] The Tier #1 and Tier #2 ranges of acceptable results are based on the standard of performance requirements set forth in Section 1220.1 (a)(1) of the Title 17 regulations. For both tests 22-5641 & 22-5642, the Tier 1 and Tier 2 limits were based on the mean values reported by all CA participating laboratories. Means for each concentration were rounded even to 3 decimal places (Banker's rule).

College of American Pathologists
Whole Blood Alcohol/Ethylene Glycol/Volatiles (2022, AL1, A - C)

	AL1-01	AL1-02[3]	AL1-03	AL1-04[3]	AL1-05
California Labs Mean	0.189	0.000	0.235	0.000	0.094
No. Participants	11	11	11	11	11
All Labs Mean	0.190	0.000	0.235	0.000	0.095
Tier# 1[2]	0.178 – 0.202	NA[3]	0.221 – 0.249	NA[3]	0.088 – 0.102
Tier #2[2]	0.17 - 0.20	NA	0.21 – 0.24	NA	0.08 – 0.10

	AL1-06	AL1-07[3]	AL1-08	AL1-09	AL1-10[3]
California Labs Mean	0.119	0.0000	0.287	0.132	0.037
No. Participants	12	12	12	12	12
All Labs Mean[2]	0.120	0.000	0.286	0.132	0.037
Tier# 1[2]	0.112 – 0.128	NA[3]	0.269 – 0.303	0.123 – 0.141	NA[3]
Tier #2[2]	0.11 – 0.13	NA	0.26 – 0.30	0.12 – 0.14	NA

	AL1-11	AL1-12	AL1-13	AL1-14	AL1-15[3]
California Labs Mean	0.041	0.280	0.057	0.209	0.000
No. Participants	11	11	11	11	11
All Labs Mean[2]	0.041	0.278	0.057	0.208	0.000
Tier# 1[2]	0.035 - 0.048	0.261 – 0.295	0.051 – 0.064	0.195 - 0.221	NA[3]
Tier #2[2]	0.03 – 0.05	0.25 – 0.29	0.05 – 0.07	0.19 - 0.22	NA

[2] The Tier #1 and Tier #2 ranges of acceptable results are based on the standard of performance requirements set forth in Section 1220.1 (a)(1) of the Title 17 regulations. For the CAP surveys, there were an insufficient number of California laboratories participating in these tests. The Tier 1 and Tier 2 limits were based on the peer group means of all laboratories (N ~175) analyzing samples in the proficiency test.

[3] Acceptable results for these items are not provided due to CAP target values to be either zero or below 0.04 gram %

Z-scores of California Laboratories on External Proficiency Tests for Alcohol Analyses 2022

Z- score is a normalized measure of a given analytical result's deviation from the consensus mean. The z-score calculated as follows:

$$Z_{ij} = \frac{\left(x_{ij} - \overline{X}_j \right)}{\sigma_{p_j}}$$

$\overline{X}_j$ – Grand mean per test item ($j = 1, 2, 3, \ldots$)

x_{ij} – Individual result reported by participant i for a given test item j

σ_{p_j} – Fitness-for-purpose standard deviation for proficiency test item j[1]

Z_{ij} – Z-score determined for each participant i and each test item j for each test

Statistical Data Used to Calculate Z-scores[2]

Table 1 Statistical Summary CTS Blood Alcohol Test 22-5641

22-5641	ITEM 1	ITEM 2	ITEM 3	ITEM 4
Mean for CA Labs (N=41[3]), $\bar{X}_i$	0.213	0.073	0.267[3]	0.130
Stand. Deviation, SD_i	0.0042	0.0022	0.0037[3]	0.0029
σ_{p_j}[1]	0.0046	0.0027	0.0052[3]	0.0036

Table 2 Statistical Summary CTS Blood Alcohol Test 21-5642

22-5642	ITEM 1	ITEM 2	ITEM 3	ITEM 4
Mean for CA Labs (N=23), $\bar{X}_i$	0.072	0.282	0.141	0.177
Stand. Deviation, SDi	0.0027	0.0050	0.0037	0.0033
σ_{p_j}[1]	0.0027	0.0053	0.0038	0.0042

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[1] $\sigma_{p_j} = 0.01 C_j^{0.5}$ where C_j is mean analyte concentration for item j either for all CA laboratories (Tables 1 and 2) or mean analyte concentration for item j for all CAP participating laboratories (Table 3). σ_p was determined using Horwitz equation (ISO 13528, Clause 7.4.2) modified by M. Thompson.

[2] Mean values were determined using round-even rules.

[3] One laboratory's raw result submitted for Item 3 was excluded (N=40 for ITEM 3 test 22-5641) because it did not correspond to the laboratory's reported results and was likely due to a transcription error.

Table 3 Statistical Summary AACC/CAP 2022 Blood Alcohol Test

AACC/CAP	AL1-01	AL1-02	AL1-03	AL1-04	AL1-05
Mean for All Labs[1] (~175), $\bar{X}_i$	0.1901	0.0000	0.2354	0.0000	0.0950
Stand. Deviation, SDi	0.0053	0.0000	0.0074	0.0000	0.0033
$\sigma_{p_j}{}^2$	0.0044	0.0000	0.0049	0.0000	0.0031

AACC/CAP	AL1-06	AL1-07	AL1-08	AL1-09	AL1-10
Mean for All Labs[1] (~170), $\bar{X}_i$	0.1197	0.0000	0.2857	0.1319	0.0370
Stand. Deviation, SD_i	0.0044	0.0000	0.0093	0.0040	0.0019
$\sigma_{p_j}{}^2$	0.0035	0.0000	0.0053	0.0036	0.0019

AACC/CAP	AL1-11	AL1-12	AL1-13	AL1-14	AL1-15
Mean for All Labs[1] (~190), $\bar{X}_i$	0.0407	0.2785	0.0569	0.2085	0.0000
Stand. Deviation, SD_i	0.0018	0.0093	0.0023	0.0071	0.0000
$\sigma_{p_j}{}^2$	0.0020	0.0053	0.0024	0.0046	0.0000

[1] There were an insufficient number of California laboratories participating in these tests to compile statistical summary based on CA labs means.

[2] $\sigma_{p_j} = 0.01C_j{}^{0.5}$ where C_j is mean analyte concentration for item j either for all CA laboratories (Tables 1 and 2) or mean analyte concentration for item j for all CAP participating laboratories (Table 3). σ_p was determined using Horwitz equation (ISO 13528, Clause 7.4.2) modified by M. Thompson.

Table 4 Statistical Summary CTS Test 22-5681 (Breath Alcohol Simulator Solution analysis)

A. CA Laboratories, Calibration port

CA labs 22-5681, Cal. Port	**BATCH A**,	N_A=10	**BATCH B,**	N_B=5
	ITEM 1	ITEM 2	ITEM 1	ITEM 2
Mean for CA Labs, N_i $\bar{X}_i$	0.140	0.254	0.143	0.268
Stand. Deviation, j=1,2	0.0023	0.0044	0.0045	0.0116

B. CA Laboratories, Breath port, Test 22-5681

CA labs 22-5681, Br. Port	**BATCH A**,	N_A=1	**BATCH B,**	N_B=4
	ITEM 1	ITEM 2	ITEM 1	ITEM 2
Mean for CA Labs, N_i $\bar{X}_i$	0.142	0.260	0.136	0.266
Stand. Deviation, j=1,2	--	--	0.0034	0.0071

C. Summary of all CTS participants results, Test 21-5681: Batch A and B, target concentrations are the same for batch A and B

Target conc.(g/210L)	**BATCH A**				**BATCH B**			
ITEM 1: 0.14	Cal.	port	Breath	port	Cal.	port	Breath	
ITEM 2: 0.26	item 1	item 2	item 1	item 2	item 1	item 2	item 1	item 2
No. of Participants, N	49	48	61	61	9	9	40	40
CTS mean	0.1415	0.2550	0.1387	0.2590	0.1415	0.2552	0.1362	0.2550
CTS STDEV	0.0022	0.0035	0.0028	0.0082	0.0023	0.0045	0.0055	0.0151

Table 5 Statistical Summary CTS Test 22-5691 (Breath Alcohol Calibration verification)

CA labs 22-5691	ITEM 1	ITEM 2	ITEM 3	ITEM 4
No. of CA labs, **N**	18	18	18	18
Mean **for CA Labs** $\bar{X}_i$	0.160	0.307	0.091	0.040
Stand. Deviation, $_{j=1,2}$	0.0023	0.0061	0.0019	0.0012

Figure 1: Z-score chart for CTS-22-5641

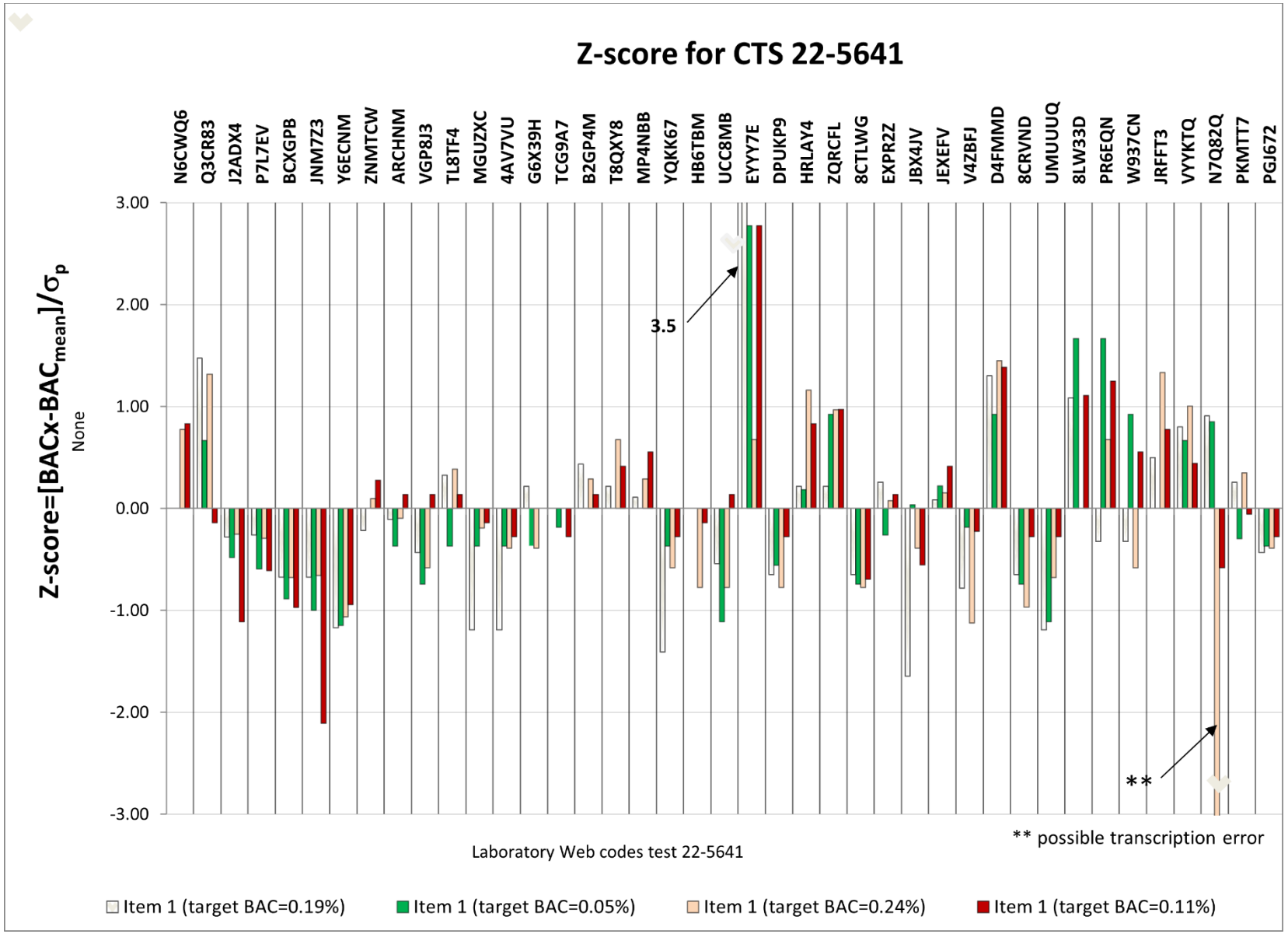

Figure 2: Z-score chart for CTS 22-5642

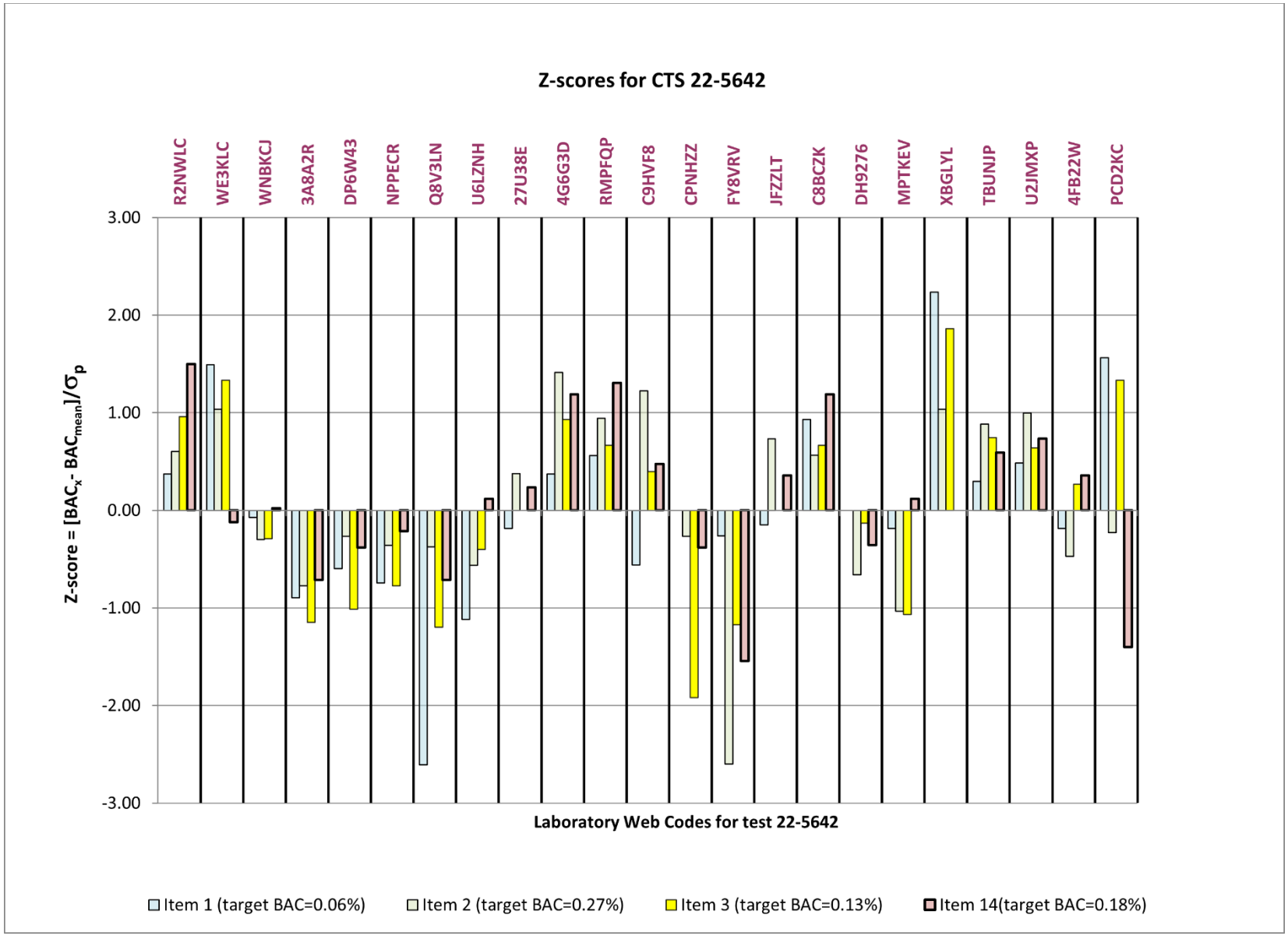

Figure 3: Z-score chart for 2022 AACC/CAP Alcohol Survey

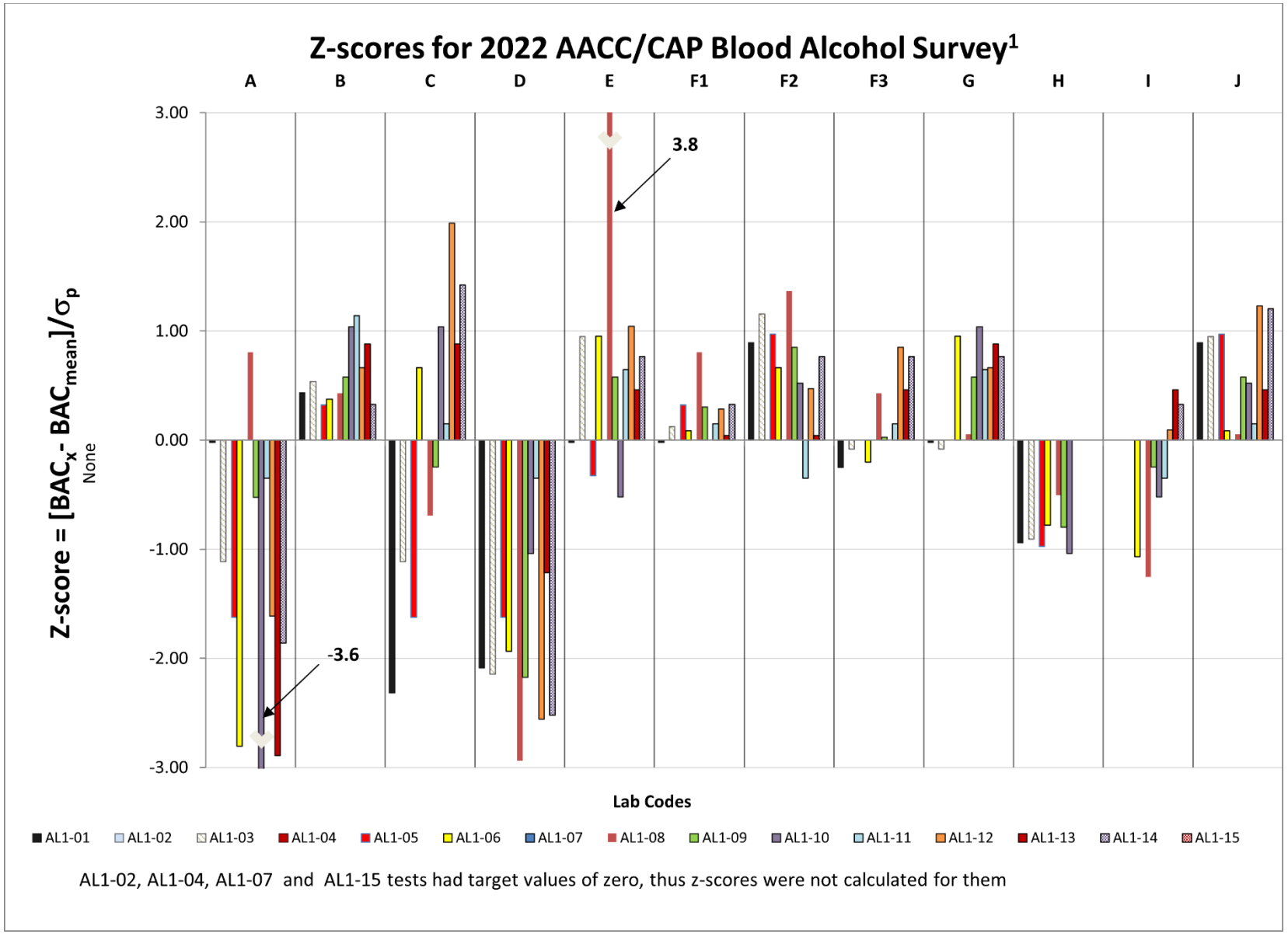

Figure 4: Z-scores chart for CTS 22-5691