

College of American Pathologists (CAP) GH5 Survey Data:

(updated 12/24)

The American Diabetes Association (ADA) recommends that “The A1C test should be performed using a method that is certified by the NGSP”. All laboratories performing HbA1c testing should participate in a fresh sample proficiency testing survey such as the College of American Pathologists (CAP). CAP GH5 data for the **third** survey of 2024 are summarized below. The NGSP target or reference values are based on replicate analyses using eight NGSP certified secondary reference methods.

Commentary by R. Little, Ph.D., NGSP Network Coordinator for the NGSP Steering Committee

Beginning in 2015 there are two CAP programs for HbA1c proficiency testing using fresh whole blood samples - GH2 and GH5. GH2 samples are shipped twice a year with three samples in each mailing as before. GH5 are shipped three times a year with five samples in each mailing. The three samples in each of the two GH2 mailings are also included in two of the GH5 mailings. Therefore, the NGSP follows the three GH5 surveys, which include all the samples used for both surveys.

In 2024, based on data from the GH5-C survey:

- **Bias from the NGSP target and variability ($\pm 2SD$) are shown in Table 1. Figure 1 shows the mean of each method compared to the NGSP/DCCT target (dotted line) for each sample. Symbols represent the mean of laboratory results for each method; error bars are $\pm 2SD$. The shaded rectangles reflect the current CAP acceptance limit of ± 6 . Graphs are in order by HbA1c level.**
- **Bias:**
 - The absolute mean bias for each method group ranged from 0.00 to 0.34% HbA1c. Two methods, Roche Cobas c513 and Roche Hitachi systems, each had a mean absolute bias $>0.3\%$ HbA1c for sample GH5-11.
- **Variability (CV)**
 - Method-specific, between-laboratory CVs ranged from 0.7% to 4.0%.
 - Unfortunately, there were 7 methods with CVs over 3.0% for one or more samples: Beckman AU Systems Beckman reagent, Roche cobas c311, Roche cobas c500 series, Roche cobas Integra 400, Roche Hitachi Systems, Siemens Atellica CI and Siemens DCA Vantage.
 - On the flip side, 18 methods had CVs $\leq 2.5\%$ for 5/5 or 3/3 samples which is the recommended interlaboratory CV§: Abbott Afinion 2, Afinion AS100, Alinity ci series, and Architect c System, Arkray Adams HA-8180 and HA-8190V, Bio-Rad D-10, D-100 and Variant II Turbo 2.0, Roche Cobas c513, Sebia Capillarys 2 Flex Piercing and Capillarys 3 Tera/Octa, Siemens Atellica CH, Dimension ExL, Dimension Vista, Tosoh G8 and G11, and Trinity Biotech Premier Hb9210 HPLC. 61% of participating laboratories are using these methods with CVs $\leq 2.5\%$.
- **Pass Rates**
 - The current pass limit for the GH5 survey is $\pm 6\%$. The overall pass rates in this survey were 96.7%, 97.2%, 97.4%, 98.2% and 96.8% for samples GH-11 through GH-15. For individual methods, the lowest pass rate was 81.8% and the highest was 100%.
 - As expected, methods with small bias and low CVs will have the highest pass rates and, conversely, methods with large bias and/or high CVs will have the lowest pass rates.
- **The overall (all-method, all-lab) CVs for the last 36 surveys are shown in Table 2. Overall CVs for the 5 samples in the current survey ranged from 2.5% to 3.0%.**
- **Laboratories should avoid using methods with high CVs and/or consistent large bias.**

- Beginning with the next survey in 2025, the NGSP will include both the new required CLIA limit of $\pm 8\%$ as well as the $\pm 6\%$ evaluation criterion that has been used for several years. The $\pm 6\%$ evaluation limit will still be used for CAP-accredited laboratories that use accuracy-based proficiency testing for HbA1c.

§ Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus are available: Diabetes Care, <https://doi.org/10.2337/dci23-0048>. Relevant to this CAP survey commentary: “The goals for imprecision for HbA1c measurement are intralaboratory CV $< 1.5\%$ and interlaboratory CV $< 2.5\%$ and ideally no measurable bias.”

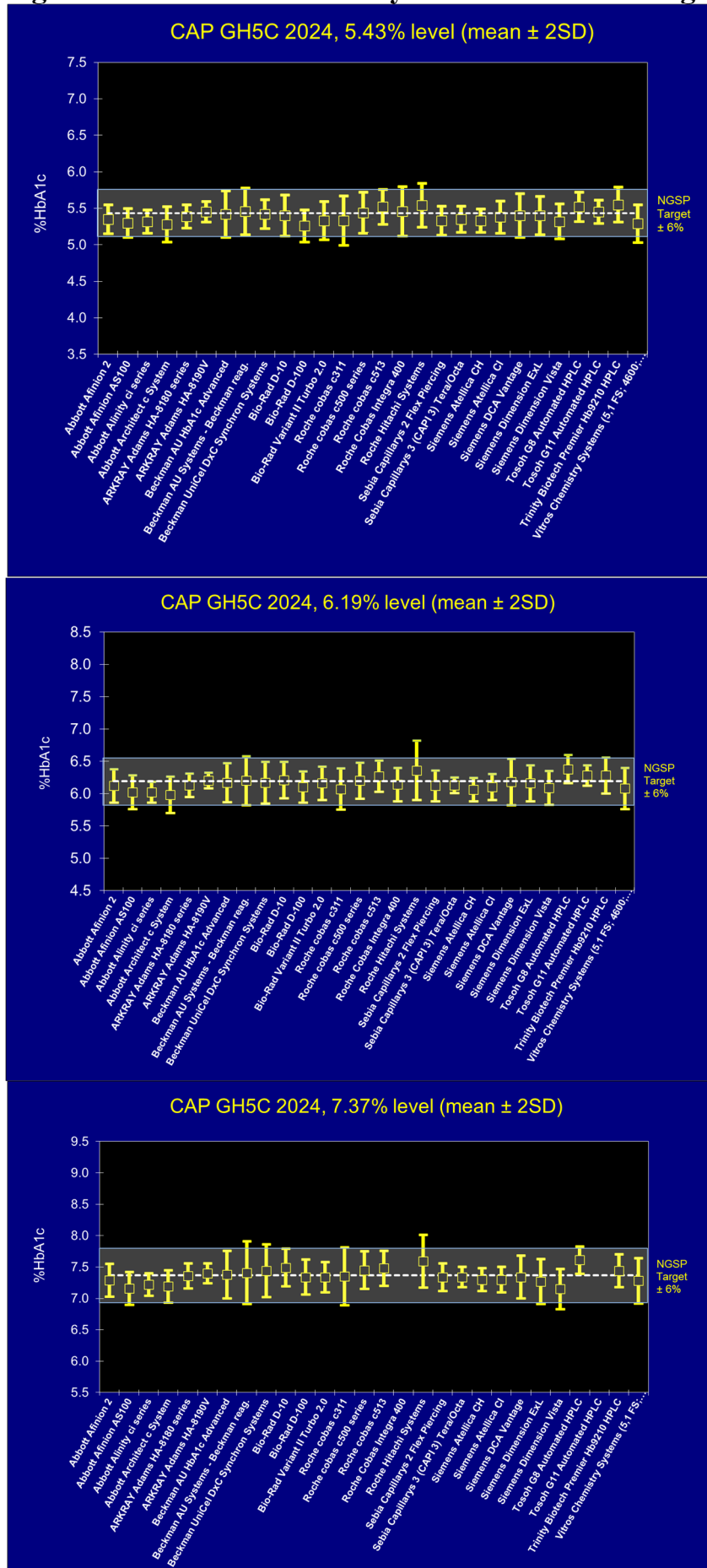
NOTE: The NGSP certification evaluates agreement of each method at the manufacturing site using one lot of reagents and calibrators, one instrument, and one application under optimal conditions. CAP precision reflects between-laboratory reproducibility, often with more than one lot of reagents and calibrators, and sometimes with different instruments (e.g. Siemens Advia instruments) and/or different applications (e.g. with or without sample pretreatment). In addition, if changes were made in the method just prior to NGSP certification, it is possible that not all participating laboratories in the field would have made the change at the time of the CAP survey. For these reasons, it is important that laboratories review not only the certification status of HbA1c methods but also their performance in the CAP survey over time (a good indication of field performance) when selecting or evaluating HbA1c assay methods.

TABLE 1: 2024 GH5-B

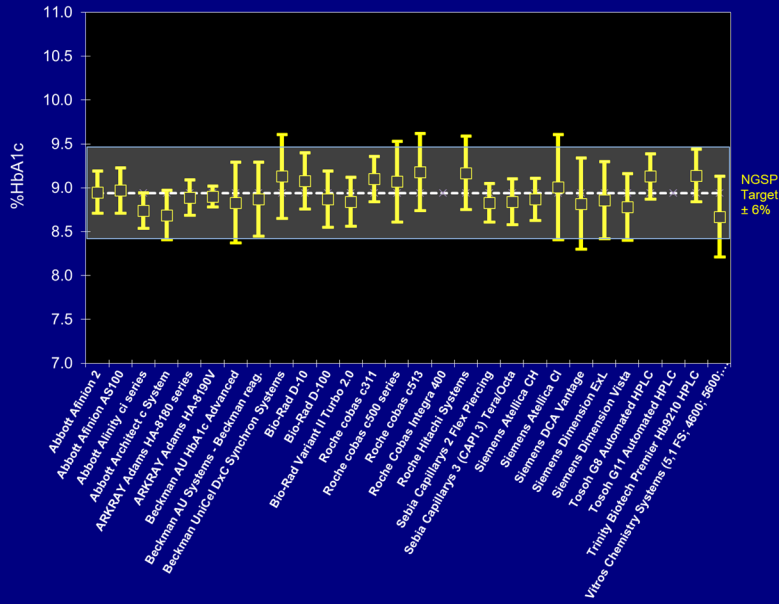
NGSP %HbA1c Reference Value (95% CI)		GH5-11			GH5-12			GH5-13			GH5-14			GH5-15		
NGSP %HbA1c Reference Value (95% CI)		10.53 (10.49-10.58)			6.19 (6.15-6.22)			5.43 (5.40-5.47)			7.37 (7.34-7.41)			8.94 (8.90-8.98)		
Method name	no. labs (GH11-GH13)	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
Abbott Afinion 2	165	10.57	0.04	1.6	6.12	-0.07	2.1	5.35	-0.08	1.9	7.29	-0.08	1.8	8.95	0.01	1.4
Abbott Afinion AS100	57	10.46	-0.07	1.9	6.02	-0.17	2.2	5.30	-0.13	2.0	7.16	-0.21	1.8	8.97	0.03	1.5
Abbott Alinity ci series	231	10.36	-0.17	0.9	6.02	-0.17	1.4	5.32	-0.11	1.5	7.22	-0.15	1.2	8.74	-0.20	1.1
Abbott Architect c System	124	10.29	-0.24	1.7	5.98	-0.21	2.3	5.28	-0.15	2.2	7.19	-0.18	1.8	8.69	-0.25	1.7
ARKRAY Adams HA-8180 series	34	10.48	-0.05	1.1	6.13	-0.06	1.5	5.39	-0.04	1.5	7.36	-0.01	1.4	8.89	-0.05	1.1
ARKRAY Adams HA-8190V	28	10.43	-0.10	0.8	6.20	0.01	1.0	5.45	0.02	1.3	7.40	0.03	1.0	8.90	-0.04	0.7
Beckman AU HbA1c Advanced	76	10.41	-0.12	2.5	6.17	-0.02	2.5	5.42	-0.01	3.0	7.38	0.01	2.6	8.83	-0.11	2.7
Beckman AU Systems - Beckman reag.	56	10.45	-0.08	2.4	6.20	0.01	3.1	5.46	0.03	2.9	7.41	0.04	3.3	8.87	-0.07	2.3
Beckman UniCel DxC Synchron Systems	23	10.83	0.30	3.0	6.17	-0.02	2.6	5.42	-0.01	1.8	7.44	0.07	2.8	9.13	0.19	2.6
Bio-Rad D-10	76	10.73	0.20	2.4	6.21	0.02	2.3	5.40	-0.03	2.5	7.49	0.12	2.0	9.08	0.14	1.7
Bio-Rad D-100	147	10.65	0.12	1.8	6.10	-0.09	1.9	5.26	-0.17	2.0	7.34	-0.03	1.9	8.87	-0.07	1.8
Bio-Rad Variant II Turbo 2.0	87	10.63	0.10	2.1	6.16	-0.03	2.1	5.33	-0.10	2.4	7.34	-0.03	1.6	8.84	-0.10	1.6
Roche cobas c311	15	10.59	0.06	2.7	6.07	-0.12	2.6	5.33	-0.1	3.2	7.35	-0.02	3.1	9.10	0.16	1.4
Roche cobas c500 series	495	10.66	0.13	3.1	6.20	0.01	2.2	5.44	0.01	2.6	7.45	0.08	2.0	9.07	0.13	2.5
Roche cobas c513	70	10.87	0.34	2.5	6.27	0.08	2.0	5.52	0.09	2.1	7.48	0.11	1.9	9.18	0.24	2.4
Roche cobas Integra 400	15	10.61	0.08	4.0	6.14	-0.05	2.2	5.46	0.03	3.2	-	-	-	-	-	-
Roche Hitachi Systems	13	10.85	0.32	2.8	6.36	0.17	3.6	5.54	0.11	2.7	7.59	0.22	2.8	9.17	0.23	2.2
Sebia Capillars 2 Flex Piercing	28	10.34	-0.19	1.6	6.12	-0.07	1.9	5.33	-0.1	1.9	7.34	-0.03	1.6	8.83	-0.11	1.2
Sebia Capillars 3 (CAPI 3) Tera/Octa	59	10.37	-0.16	1.6	6.13	-0.06	1.1	5.35	-0.08	1.6	7.34	-0.03	1.1	8.84	-0.10	1.5
Siemens Atellica CH	173	10.53	0.00	1.1	6.06	-0.13	1.5	5.33	-0.1	1.6	7.30	-0.07	1.2	8.87	-0.07	1.3
Siemens Atellica CI	14	10.49	-0.04	1.3	6.10	-0.09	1.7	5.38	-0.05	2.1	7.30	-0.07	1.4	9.01	0.07	3.3
Siemens DCA Vantage	255	10.44	-0.09	3.7	6.18	-0.01	3.0	5.40	-0.03	2.9	7.34	-0.03	2.3	8.82	-0.12	3.0
Siemens Dimension ExL	141	10.57	0.04	2.1	6.16	-0.03	2.3	5.40	-0.03	2.4	7.27	-0.10	2.4	8.86	-0.08	2.5
Siemens Dimension Vista	83	10.42	-0.11	2.1	6.09	-0.10	2.2	5.32	-0.11	2.3	7.15	-0.22	2.2	8.78	-0.16	2.1
Tosoh G8 Automated HPLC	237	10.82	0.29	1.5	6.38	0.19	1.7	5.52	0.09	1.8	7.61	0.24	1.5	9.13	0.19	1.4
Tosoh G11 Automated HPLC	12	10.57	0.04	1.2	6.28	0.09	1.2	5.45	0.02	1.5	-	-	-	-	-	-
Trinity Biotech Premier Hb9210 HPLC	69	10.76	0.23	1.7	6.28	0.09	2.3	5.55	0.12	2.2	7.44	0.07	1.7	9.14	0.20	1.7
Vitros Chemistry Systems (5,1 FS; 4600; 5600; XT 3400; XT 7600)	203	10.24	-0.29	2.9	6.08	-0.11	2.7	5.29	-0.14	2.5	7.28	-0.09	2.5	8.67	-0.27	2.7

Gray shading indicates bias > 0.3% HbA1c or CV > 3.0%. Note: these are arbitrary limits chosen to highlight methods with the highest bias and CV.

Figure 1: Bias and Variability from the NGSP Target



CAP GH5C 2024, 8.94% level (mean \pm 2SD)



CAP GH5C 2024, 10.53% level (mean \pm 2SD)

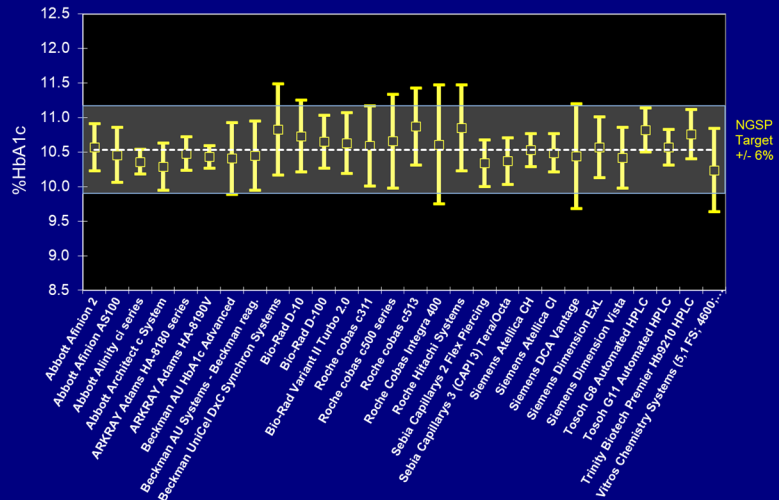


Table 2: Overall Variability for 2010-2023 for all GH participants

Mailing	Sample#	# of labs	Target	All method mean	S.D.	C.V.
A-2010	01	2573	5.9	6.03	0.23	3.9
	02	2566	9.8	9.73	0.39	4.0
	03	2581	7.4	7.43	0.31	4.2
B-2010	04	2693	5.2	5.34	0.21	4.0
	05	2691	8.7	8.67	0.33	3.8
	06	2685	6.3	6.37	0.23	3.5
A-2011	01	2652	8.5	8.58	0.28	3.2
	02	2645	5.4	5.52	0.20	3.5
	03	2649	6.4	6.51	0.21	3.2
B-2011	04	2877	6.3	6.36	0.24	3.8
	05	2872	7.6	7.69	0.29	3.8
	06	2871	9.2	9.28	0.34	3.7
A 2012	01	3298	5.6	5.62	0.20	3.5
	02	3316	9.4	9.44	0.37	3.9
	03	3301	7.2	7.28	0.29	3.9
B2012	04	3222	5.4	5.51	0.21	3.9
	05	3208	8.3	8.31	0.31	3.7
	06	3172	5.65	5.75	0.32	5.6
A 2013	01	2816	7.1	7.12	0.25	3.5
	02	2829	9.3	9.39	0.31	3.3
	03	2840	6.1	6.13	0.24	3.9
B2013	04	2912	8.1	8.04	0.31	3.8
	05	2907	5.3	5.33	0.20	3.8
	06	2908	6.1	6.17	0.24	3.9
A2014	01	3277	6.5	6.60	0.25	3.8
	02	3267	7.0	7.09	0.27	3.8
	03	3253	9.7	9.72	0.33	3.4
B2014	04	3278	6.58	6.64	0.23	3.5
	05	3273	8.39	8.45	0.30	3.6
	06	3266	5.65	5.67	0.21	3.6
A2015	01	3237	6.79	6.82	0.25	3.6
	02	3246	10.28	10.19	0.36	3.5
	03	3252	6.82	6.82	0.25	3.6
	04	2365	8.63	8.63	0.30	3.4
	05	2362	5.32	5.36	0.18	3.4
B2015	06	2379	5.84	5.87	0.2	3.5
	07	2392	11.71	11.68	0.44	3.8
	08	2402	9.53	9.5	0.33	3.5
	09	2386	5.04	5.08	0.17	3.4
	10	2403	7.38	7.35	0.26	3.5
C2015	11	3284	11.69	11.68	0.47	4.1
	12	3285	5.93	5.95	0.19	3.3
	13	3286	5.17	5.2	0.17	3.3
	14	2410	8.14	8.12	0.24	2.9
	15	2408	9.3	9.25	0.29	3.2
A2016	01	3358	5.32	5.33	0.16	3.1
	02	3365	9.17	9.21	0.28	3.0

	03	3357	5.31	5.33	0.16	3.1
	04	2425	12.03	12.12	0.40	3.3
	05	2419	5.94	5.96	0.16	2.8
B2016	06	2433	5.27	5.27	0.15	2.8
	07	2427	10.59	10.55	0.33	3.1
	08	2440	6.20	6.17	0.18	2.9
	09	2428	12.23	12.21	0.44	3.6
	10	2443	7.51	7.52	0.20	2.7
C2016	11	3377	9.11	9.08	0.24	2.6
	12	3402	6.01	5.99	0.16	2.6
	13	3372	11.71	11.69	0.39	3.4
	14	2432	5.02	5.02	0.16	3.2
	15	2442	7.58	7.58	0.19	2.5
A2017	01	3418	6.41	6.45	0.2	3.1
	02	3393	9.53	9.56	0.28	2.9
	03	3409	5.34	5.35	0.17	3.1
	04	2461	8.51	8.58	0.23	2.7
	05	2460	7.25	7.33	0.19	2.6
B2017	06	2446	7.42	7.49	0.22	3.0
	07	2445	5.2	5.22	0.19	3.6
	08	2450	8.31	8.33	0.21	2.5
	09	2443	10.33	10.38	0.31	3.0
	10	2457	5.87	5.91	0.19	3.2
C2017	11	3331	7.25	7.28	0.19	2.6
	12	3339	6.81	6.85	0.2	3.0
	13	3344	8.65	8.64	0.23	2.6
	14	2431	9.5	9.54	0.26	2.8
	15	2419	5.45	5.45	0.16	2.9
A2018	01	3371	7.15	7.16	0.21	3.0
	02	3343	5.19	5.20	0.19	3.6
	03	3369	8.42	8.39	0.24	2.9
	04	2466	9.79	9.75	0.29	2.9
	05	2473	6.12	6.13	0.18	3.0
B2018	06	2442	6.31	6.34	0.19	2.9
	07	2443	9.11	9.09	0.25	2.8
	08	2446	5.31	5.30	0.15	2.9
	09	2448	8.35	8.40	0.21	2.5
	10	2446	7.62	7.64	0.19	2.5
C2018	11	3311	9.37	9.31	0.27	3.0
	12	3291	4.92	4.96	0.16	3.2
	13	3300	6.04	6.09	0.18	3.0
	14	2463	5.28	5.32	0.17	3.1
	15	2469	8.08	8.11	0.24	3.0
A2019	01	3136	5.46	5.45	0.20	3.6
	02	3089	5.66	5.71	0.25	4.4
	03	3232	9.31	9.29	0.29	3.1
	04	2470	5.28	5.24	0.17	3.3
	05	2482	7.41	7.43	0.20	2.7

B2019	06	2462	6.41	6.44	0.18	2.8
	07	2460	8.60	8.66	0.29	3.3
	08	2461	5.42	5.41	0.16	2.9
	09	2467	7.38	7.44	0.19	2.6
	10	2457	9.75	9.77	0.31	3.2
C2019	11	3268	5.25	5.20	0.16	3.0
	12	3283	6.41	6.44	0.19	3.0
	13	3283	8.21	8.23	0.24	2.9
	14	2463	5.47	5.45	0.15	2.8
	15	2461	9.48	9.50	0.28	3.0
A2020	01	2862	7.97	8.06	0.22	2.7
	02	2976	5.89	5.92	0.16	2.7
	03	2962	5.13	5.11	0.15	2.9
	04	2311	7.40	7.43	0.22	2.9
	05	2328	9.17	9.17	0.25	2.7
B2020	06	2392	7.81	7.80	0.20	2.6
	07	2398	5.91	5.90	0.18	3.0
	08	2394	8.69	8.69	0.25	2.8
	09	2408	5.86	5.90	0.18	3.1
	10	2396	9.56	9.52	0.30	3.1
C2020	11	3197	5.48	5.46	0.16	2.9
	12	3204	8.26	8.26	0.22	2.7
	13	3209	5.15	5.11	0.14	2.8
	14	2403	10.05	10.07	0.28	2.8
	15	2411	5.99	5.97	0.16	2.7
B2021	06	2408	5.80	5.77	0.17	3.0
	07	2402	9.12	9.12	0.24	2.6
	08	2402	5.47	5.43	0.14	2.6
	09	2408	7.25	7.23	0.19	2.6
	10	2398	9.26	9.28	0.25	2.7
C2021	11	3156	5.21	5.16	0.14	2.7
	12	3176	6.68	6.66	0.16	2.4
	13	3159	-----	8.32	0.34	4.0
	14	2382	5.98	5.97	0.14	2.4
	15	2392	10.12	10.15	0.26	2.6
A2022	01	3121	8.42	8.44	0.23	2.7
	02	3127	6.31	6.31	0.14	2.2
	03	3131	9.05	9.12	0.24	2.7
	04	2411	5.18	5.14	0.13	2.5
	05	2410	6.72	6.72	0.15	2.2
B2022	06	2393	5.93	5.91	0.15	2.5
	07	2393	8.92	8.96	0.22	2.5
	08	2405	5.44	5.39	0.14	2.5
	09	2390	7.33	7.34	0.19	2.6
	10	2382	9.37	9.42	0.23	2.4
C2022	11	2903	5.09	5.04	0.14	2.8
	12	2953	6.91	6.93	0.18	2.6
	13	2906	8.84	8.90	0.24	2.7
	14	2348	9.98	10.03	0.24	2.4
	15	2308	5.52	5.47	0.14	2.6
A2023	01	3012	7.58	7.51	0.20	2.7
	02	3007	8.88	8.84	0.22	2.5
	03	3012	5.82	5.78	0.17	2.9
	04	2374	10.00	9.97	0.23	2.4
	05	2382	5.24	5.17	0.15	3.0
B2023	06	2415	9.21	9.26	0.22	2.4
	07	2426	6.09	6.06	0.17	2.8
	08	2410	8.75	8.79	0.24	2.7
	09	2421	5.11	5.09	0.14	2.8
	10	2419	8.09	8.09	0.21	2.6

C2023	11	3089	5.53	5.52	0.16	2.9
	12	3084	5.26	5.24	0.15	2.9
	13	3088	6.49	6.49	0.18	2.8
	14	2413	8.37	8.33	0.23	2.8
	15	2420	10.11	10.04	0.30	2.9
A2024	01	3070	5.32	5.29	0.16	3.0
	02	3059	7.24	7.23	0.20	2.8
	03	3072	8.92	8.95	0.25	2.8
	04	2428	6.47	6.48	0.17	2.7
	05	2417	9.95	9.99	0.26	2.6
B2024	06	2462	7.68	7.72	0.21	2.7
	07	2454	9.87	9.89	0.26	2.7
	08	2466	6.55	6.52	0.18	2.8
	09	2450	8.99	9.01	0.24	2.7
	10	2458	5.35	5.30	0.16	3.0
C2024	11	3049	10.53	10.54	0.31	3.0
	12	3018	6.19	6.15	0.17	2.8
	13	3040	5.43	5.39	0.15	2.8
	14	2424	7.37	7.37	0.19	2.5
	15	2431	8.94	8.92	0.24	2.7

CVs **below** 3.5% are highlighted in pink

CVs **below** 3.0% are highlighted in blue

HbAS samples is indicated in yellow

There is no assigned value for GH13 due to an unusual amount of variability found during value assignment. Interestingly, there was also a higher than usual variability seen in the all method CV%.