College of American Pathologists (CAP) GH5 Survey Data:

(updated 08/25)

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 **second** survey of 2025 are summarized below. The NGSP target or reference values are based on replicate analyses using eight NGSP certified secondary reference methods.

Commentary by C. Rohlfing, NGSP Network Coordinator for the NGSP Steering Committee

GH5 survey samples are shipped three times a year with five samples in each mailing.

In 2025, based on data from the GH5-B survey:

- **Bias from the NGSP target and variability (±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 ±2SD. The shaded rectangles reflect the current CAP accreditation limit of ±6%. Graphs are in order by HbA1c level.**
- **Bias:**
  - **The absolute mean bias for each method group ranged from 0.00 to 0.39% HbA1c. Five methods, the Bio-Rad D-10 and Variant II, Roche cobas c513, Tosoh G8 and Ortho Vitros had a bias of >0.3% HbA1c for sample GH5-08. One method, the Siemens Dimension Vista, had a bias >0.3% HbA1c for sample GH5-10.**
- **Variability (CV)**
  - **Method-specific, between-laboratory CVs ranged from 0.6% to 5.5%.**
  - **There were 8 methods with CVs over 3.0% for one or more samples: Beckman AU Systems Advanced and Beckman reagent, Beckman UniCel DxC Synchron, Bio-Rad Variant II, Roche cobas c311 and Hitachi Systems, Siemens DCA Vantage and Ortho Vitros.**
  - **On the flip side, 17 methods had CVs ≤2.5% for 5/5 samples which is the recommended interlaboratory CV§: Abbott Afinion 2 and AS100, Abbott Alinity ci series, and Architect c System, Arkray Adams HA-8180 and HA-8190V, Bio-Rad D-10 and D-100, Roche Cobas c513, Sebia Capillarys 2 Flex Piercing and Capillarys 3 Tera/Octa, Siemens Atellica CH, Atellica CI, Dimension ExL and Dimension Vista, and Tosoh G8 and G11. 58% of participating laboratories are using these methods with CVs ≤2.5%.**
- **Pass Rates**
  - **The current accreditation limit for the GH5 survey is ±6%. The overall ±6% pass rates in this survey were 97.2%, 98.4%, 97.0%, 98.3% and 97.7% for samples GH-06 through GH-10. For individual methods, the lowest pass rate was 70% 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 38 surveys are shown in Table 2. Overall CVs for the 5 samples in the current survey ranged from 2.5% to 2.8%.**
- **Laboratories should avoid using methods with high CVs and/or consistent large bias.**

§ 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."

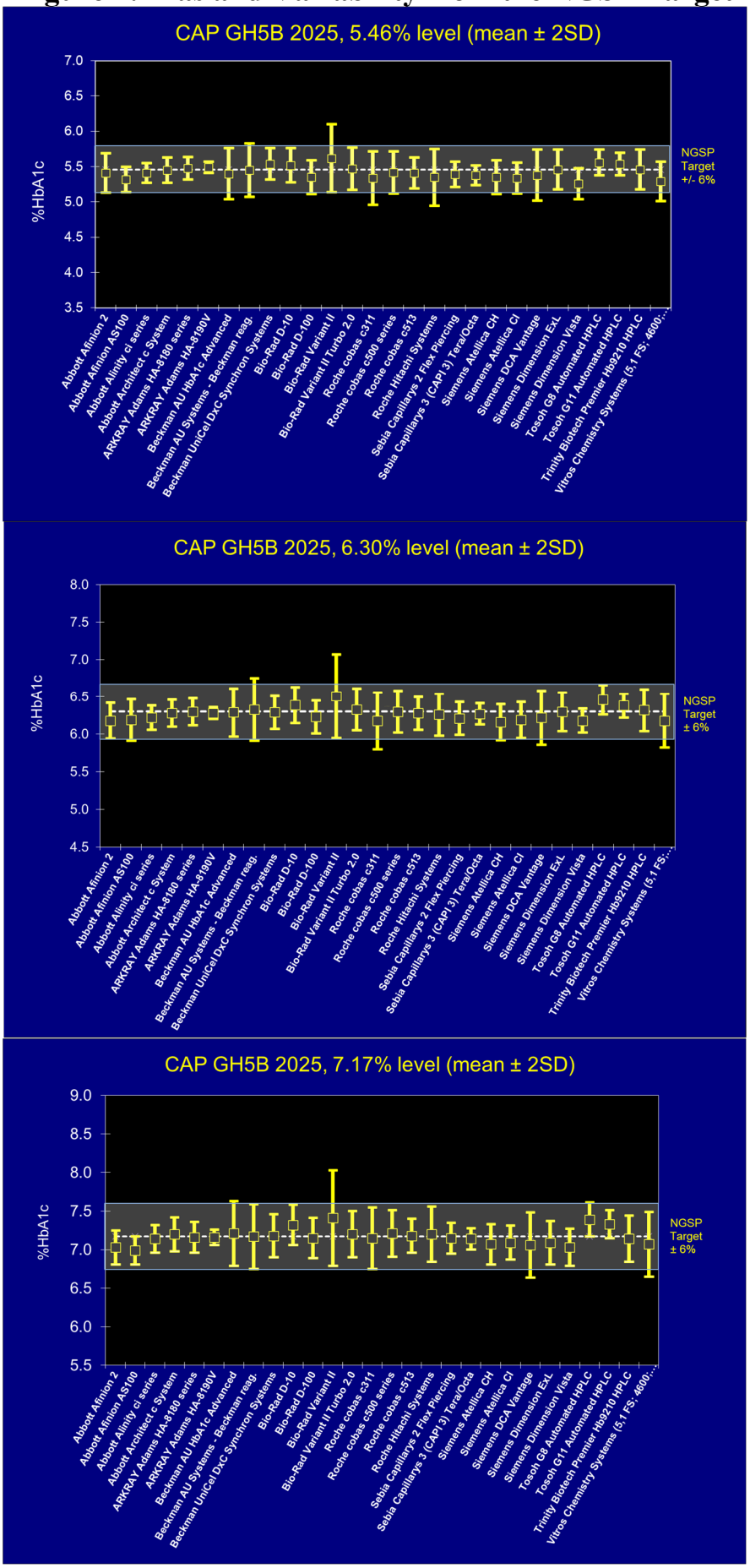
NOTE: The NGSP certification evaluates agreement of each method at the manufacturing site using one lot of reagents and calibrators, one instrument, and one application under optimal conditions. CAP precision reflects between-laboratory reproducibility, often with more than one lot of reagents and calibrators, and sometimes with different instruments (e.g. Siemens Dimension 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.

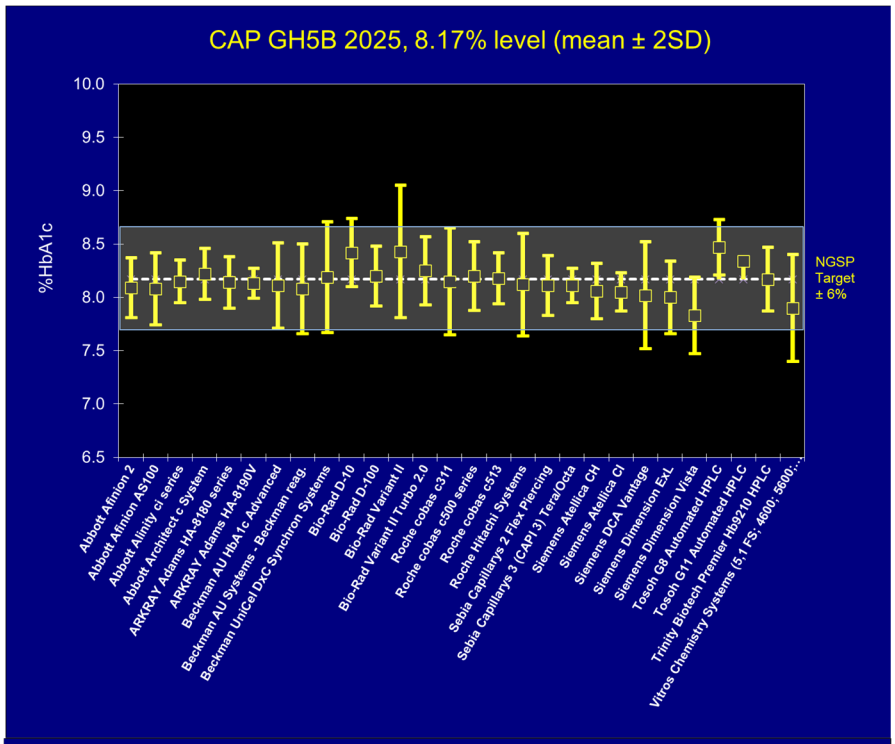
TABLE 1: 2025 GH5-B

		GH5-06			GH5-07			GH5-08			GH5-09			GH5-10		
NGSP %HbA1c Reference Value (95% CI)		**5.46 (5.41-5.52)**			**7.17 (7.11-7.23)**			**9.92 (9.87-9.98)**			**6.30 (6.24-6.35)**			**8.17 (8.12-8.23)**		
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	71	5.41	-0.05	2.5	7.03	-0.14	1.6	9.82	-0.10	1.7	6.18	-0.12	2.0	8.09	-0.08	1.7
Abbott Afinion AS100	17	5.32	-0.14	1.7	6.99	-0.18	1.3	9.74	-0.18	1.5	6.19	-0.11	2.2	8.08	-0.09	2.1
Abbott Alinity ci series	263	5.41	-0.05	1.3	7.14	-0.03	1.2	9.93	0.01	1.3	6.22	-0.08	1.3	8.15	-0.02	1.2
Abbott Architect c System	112	5.45	-0.01	1.7	7.20	0.03	1.5	10.02	0.10	1.4	6.28	-0.02	1.4	8.22	0.05	1.4
ARKRAY Adams HA-8180 series	30	5.48	0.02	1.5	7.16	-0.01	1.4	9.90	-0.02	1.4	6.30	0.00	1.5	8.14	-0.03	1.5
ARKRAY Adams HA-8190V	15	5.49	0.03	0.6	7.16	-0.01	0.7	9.89	-0.03	0.8	6.28	-0.02	0.7	8.13	-0.04	0.9
Beckman AU HbA1c Advanced	93	5.40	-0.06	3.3	7.21	0.04	2.8	9.83	-0.09	2.6	6.29	-0.01	2.6	8.11	-0.06	2.5
Beckman AU Systems - Beckman reag.	44	5.45	-0.01	3.5	7.17	0.00	3.0	9.80	-0.12	2.7	6.33	0.03	3.3	8.08	-0.09	2.6
Beckman UniCel DxC Synchron Systems	18	5.54	0.08	2.1	7.18	0.01	1.9	10.13	0.21	1.4	6.29	-0.01	1.7	8.19	0.02	3.2
Bio-Rad D-10	69	5.52	0.06	2.1	7.32	0.15	1.8	10.23	0.31	2.3	6.39	0.09	1.9	8.42	0.25	1.9
Bio-Rad D-100	135	5.35	-0.11	2.2	7.15	-0.02	1.8	10.01	0.09	1.7	6.23	-0.07	1.8	8.20	0.03	1.6
Bio-Rad Variant II	10	5.62	0.16	4.3	7.41	0.24	4.2	10.31	0.39	3.6	6.51	0.21	4.3	8.43	0.26	3.6
Bio-Rad Variant II Turbo 2.0	84	5.47	0.01	2.7	7.20	0.03	2.1	10.05	0.13	1.9	6.33	0.03	2.3	8.25	0.08	2.0
Roche cobas c311	11	5.34	-0.12	3.6	7.15	-0.02	2.8	10.04	0.12	3.1	6.18	-0.12	3.1	8.15	-0.02	3.1
Roche cobas c500 series	464	5.42	-0.04	2.8	7.21	0.04	2.0	10.08	0.16	2.5	6.30	0.00	2.1	8.20	0.03	2.0
Roche cobas c513	62	5.41	-0.05	2.1	7.18	0.01	1.6	10.24	0.32	1.6	6.28	-0.02	1.7	8.18	0.01	1.5
Roche Hitachi Systems	13	5.35	-0.11	3.7	7.20	0.03	2.4	10.18	0.26	5.5	6.26	-0.04	2.2	8.12	-0.05	3.0
Sebia Capillarys 2 Flex Piercing	24	5.39	-0.07	1.7	7.15	-0.02	1.4	9.81	-0.11	1.6	6.21	-0.09	1.7	8.11	-0.06	1.7
Sebia Capillarys 3 (CAPI 3) Tera/Octa	56	5.38	-0.08	1.4	7.14	-0.03	0.9	9.86	-0.06	1.2	6.27	-0.03	1.1	8.11	-0.06	1.0
Siemens Atellica CH	184	5.35	-0.11	2.3	7.07	-0.10	1.8	9.82	-0.10	1.4	6.16	-0.14	1.9	8.06	-0.11	1.6
Siemens Atellica CI	19	5.34	-0.12	2.1	7.09	-0.08	1.6	9.82	-0.10	1.2	6.19	-0.11	1.9	8.05	-0.12	1.2
Siemens DCA Vantage	75	5.38	-0.08	3.4	7.06	-0.11	3.0	9.77	-0.15	3.7	6.22	-0.08	2.9	8.02	-0.15	3.1
Siemens Dimension ExL	120	5.46	0.00	2.5	7.09	-0.08	1.9	9.94	0.02	2.3	6.30	0.00	2.1	8.00	-0.17	2.1
Siemens Dimension Vista	61	5.26	-0.20	2.1	7.03	-0.14	1.7	9.94	0.02	1.8	6.18	-0.12	1.3	7.83	-0.34	2.3
Tosoh G8 Automated HPLC	214	5.56	0.10	1.6	7.39	0.22	1.5	10.26	0.34	1.4	6.46	0.16	1.5	8.47	0.30	1.6
Tosoh G11 Automated HPLC	11	5.54	0.08	1.5	7.33	0.16	1.2	10.05	0.13	1.1	6.38	0.08	1.2	8.34	0.17	1.1
Trinity Biotech Premier Hb9210 HPLC	60	5.46	0.00	2.6	7.14	-0.03	2.1	9.89	-0.03	1.7	6.32	0.02	2.2	8.17	0.00	1.9
Vitros Chemistry Systems (5,1 FS; 4600; 5600; XT 3400; XT 7600)	184	5.29	-0.17	2.7	7.07	-0.10	2.9	9.61	-0.31	3.1	6.18	-0.12	2.9	7.90	-0.27	3.2

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 GH5B 2025, 8.17% level (mean ± 2SD)
%HbA1c
10.0
9.5
9.0
8.5
8.0
7.5
7.0
6.5
NGSP Target ± 6%
Abbott Afinion 2
Abbott Afinion AS100
Abbott Alinity ci series
Abbott Architect c System
ARKRAY Adams HA-8180 series
ARKRAY Adams HA-8190V
Beckman AU HbA1c Advanced
Beckman AU Systems - Beckman reag.
Beckman UniCel DxC Synchron Systems
Bio-Rad D-10
Bio-Rad D-100
Bio-Rad Variant II
Bio-Rad Variant II Turbo 2.0
Roche cobas c311
Roche cobas c500 series
Roche cobas c513
Roche Hitachi Systems
Sebia Capillarys 2 Flex Piercing
Sebia Capillarys 3 (CAPI 3) TeraOcta
Siemens Atellica CH
Siemens Atellica CI
Siemens DCA Vantage
Siemens Dimension ExL
Siemens Dimension Vista
Tosoh G8 Automated HPLC
Tosoh G11 Automated HPLC
Trinity Biotech Premier Hb9210 HPLC
Vitros Chemistry Systems (5,1 FS; 4600; 5600;...

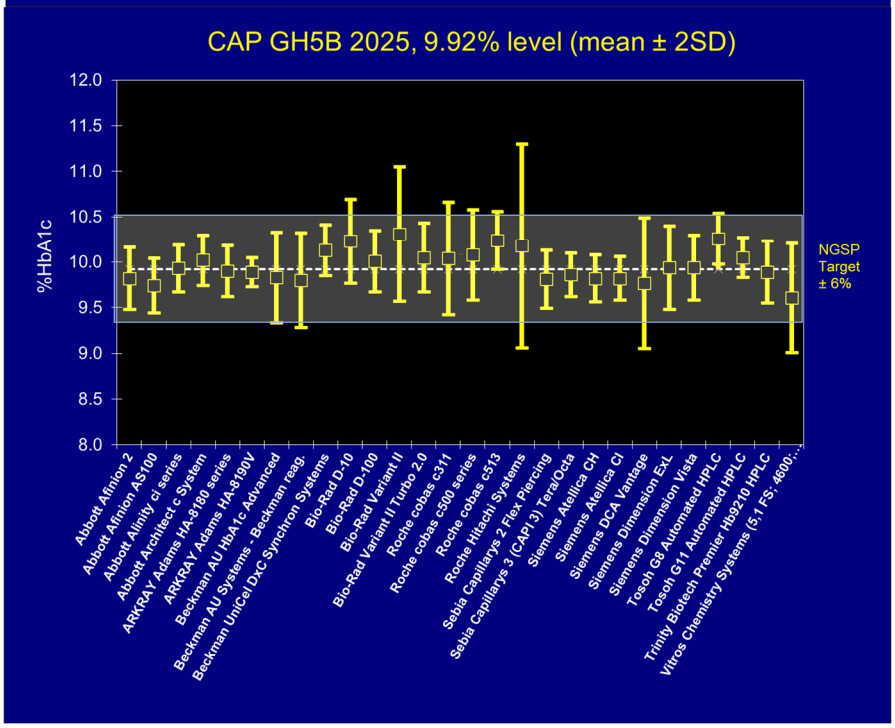

CAP GH5B 2025, 9.92% level (mean ± 2SD)
%HbA1c
12.0
11.5
11.0
10.5
10.0
9.5
9.0
8.5
8.0
NGSP Target ± 6%
Abbott Afinion 2
Abbott Afinion AS100
Abbott Alinity ci series
Abbott Architect c System
ARKRAY Adams HA-8180 series
ARKRAY Adams HA-8190V
Beckman AU HbA1c Advanced
Beckman AU Systems - Beckman reag.
Beckman UniCel DxC Synchron Systems
Bio-Rad D-10
Bio-Rad D-100
Bio-Rad Variant II
Bio-Rad Variant II Turbo 2.0
Roche cobas c311
Roche cobas c500 series
Roche cobas c513
Roche Hitachi Systems
Sebia Capillarys 2 Flex Piercing
Sebia Capillarys 3 (CAPI 3) TeraOcta
Siemens Atellica CH
Siemens Atellica CI
Siemens DCA Vantage
Siemens Dimension ExL
Siemens Dimension Vista
Tosoh G8 Automated HPLC
Tosoh G11 Automated HPLC
Trinity Biotech Premier Hb9210 HPLC
Vitros Chemistry Systems (5,1 FS; 4600;...

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
A2025	01	2635	9.84	9.85	0.28	2.8
	02	2631	5.60	5.55	0.14	2.5
	03	2642	7.97	7.94	0.21	2.6
	04	2633	8.45	8.46	0.22	2.6
	05	2624	6.00	5.95	0.16	2.7
B2025	06	2589	5.46	5.41	0.15	2.7
	07	2584	7.17	7.17	0.17	2.4
	08	2585	9.92	9.97	0.27	2.7
	09	2589	6.30	6.27	0.15	2.4
	10	2593	8.17	8.15	0.22	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 that usual variability seen in the all method CV%.