College of American Pathologists (CAP) GH5 Survey Data:

(updated 1/23)

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 2022 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 2022, based on data from the GH5-C survey:

- **Bias from the NGSP target and variability (±2SD) are shown in Table 1 and in figure 1 (Figure 1 graphs in order by HbA1c level) for each method. The shaded rectangle (fig 1) reflects the current CAP acceptance limit of ±6.**
- **Bias:**
  - **The absolute mean bias for each method group ranged from 0 to 0.26% HbA1c.**
  - **None of the methods had an absolute mean bias of >0.26% HbA1c.**
- **Variability (CV)**
  - **Method-specific, between-laboratory CVs ranged from 0.7% to 4.7%.**
  - **There were 8 methods with CVs over 3.0% for one or more samples: Beckman AU HbA1c, Bio-Rad D-10, Bio-Rad Variant II Turbo 2.0, Bio-Rad Variant II, Ortho Clinical Vitros 5,1 FS, Roche cobas c311, Sebia Capillarys 2 and Siemens DCA Vantage.**
  - **There were 7 methods with CVs ≤2% for 5/5 or 3/3 samples– the Abbott Alinity ci and Architect c, Arkray Adams HA-8180 and HA-8190V, Siemens Atellica CH enzymatic reagent, and Tosoh G8 and G11. Less than 1/3 of participating laboratories are using these methods with CVs ≤2%.**
  - **Only 77% of laboratories are using methods with between-lab CVs ≤3% for 5/5 or 3/3 HbA1c levels.**
  - **CVs for individual methods were somewhat higher in this survey compared to the previous survey.**
- **Pass Rates**
  - **The current pass limit for the GH5 survey is ±6%. The overall pass rates in this survey were 97.7%, 98.2%, 97.0%, 97.4% and 98.2% for samples GH-11 through GH-15. For individual methods, the lowest pass rate was 90.0% 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 31 surveys are shown in Table 2. Overall CVs for the 5 samples in the current survey ranged from 2.4% to 2.8%; ALL WERE LESS THAN 3%.**
- **Laboratories should avoid using methods with high CVs and/or consistent large bias.**

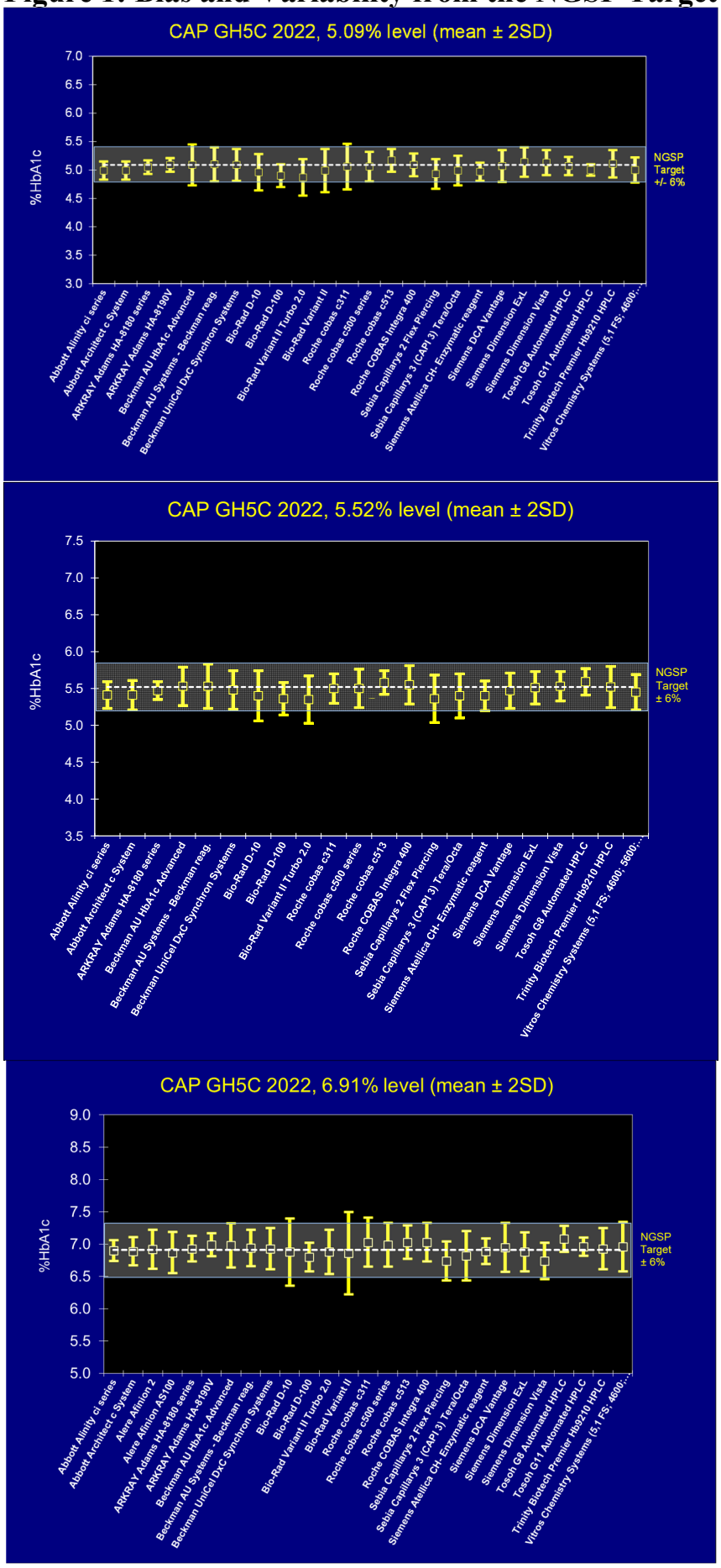
NOTE: The NGSP certification evaluates agreement of each method at the manufacturing site using one lot of reagents and calibrators, one instrument, and one application under optimal conditions. CAP precision reflects between-laboratory reproducibility, often with more than one lot of reagents and calibrators,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

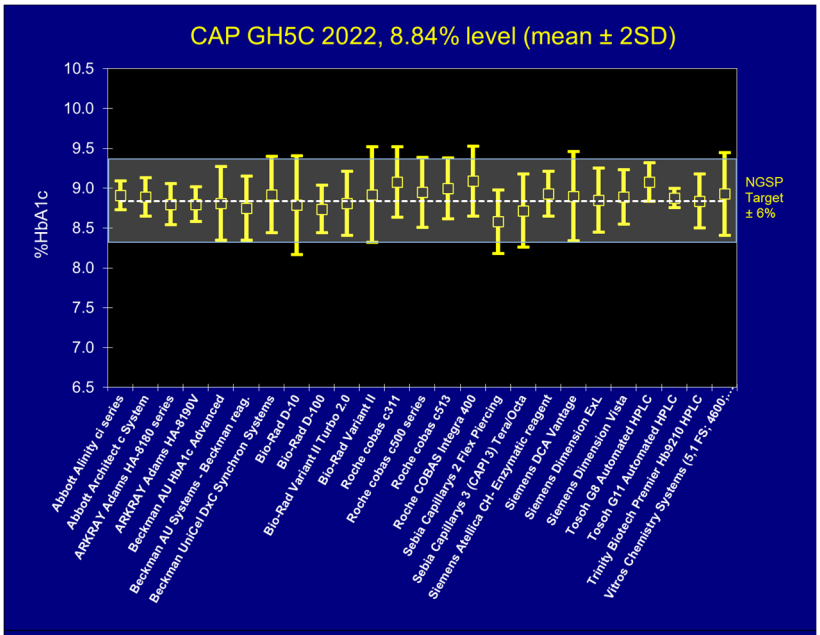
TABLE 1: 2022 GH5-C

		GH5-11			GH5-12			GH5-13			GH5-14			GH5-15		
NGSP %HbA1c Reference Value (95% CI)		5.09 (5.05-5.13)			6.91 (6.87-6.94)			8.84 (8.80-8.88)			9.98 (9.93-10.02)			5.52 (5.49-5.56)		
Method name	no. labs (GH-11-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 Alinity ci series	133	4.99	-0.10	1.5	6.9	-0.01	1.2	8.91	0.07	1	10.06	0.08	1	5.41	-0.11	1.6
Abbott Architect c System	209	4.99	-0.10	1.7	6.89	-0.02	1.6	8.89	0.05	1.3	10.04	0.06	1.5	5.41	-0.11	1.8
Alere Afinion 2	22				6.92	0.01	2.2				10.06	0.08	3	-	-	-
Alere Afinion AS100	24				6.87	-0.04	2.3				-	-	-	-	-	-
ARKRAY Adams HA-8180 series	31	5.05	-0.04	1.1	6.93	0.02	1.5	8.8	-0.04	1.4	9.91	-0.07	1.2	5.47	-0.05	1.2
ARKRAY Adams HA-8190V	10	5.09	0.00	1.1	6.99	0.08	1.3	8.8	-0.04	1.2	-	-	-	-	-	-
Beckman AU HbA1c Advanced	40	5.09	0.00	3.4	6.98	0.07	2.5	8.81	-0.03	2.6	9.88	-0.1	2.6	5.53	0.01	2.3
Beckman AU Systems - Beckman reag.	65	5.1	0.01	3	6.94	0.03	2.1	8.75	-0.09	2.3	9.92	-0.06	2.8	5.53	0.01	2.7
Beckman UniCel DxC Synchron Systems	53	5.09	0.00	2.7	6.93	0.02	2.3	8.92	0.08	2.6	10.09	0.11	2.7	5.48	-0.04	2.4
Bio-Rad D-10	104	4.96	-0.13	3.3	6.88	-0.03	3.8	8.79	-0.05	3.5	10.05	0.07	2.9	5.4	-0.12	3.1
Bio-Rad D-100	133	4.9	-0.19	2	6.8	-0.11	1.6	8.74	-0.10	1.7	9.87	-0.11	1.9	5.36	-0.16	2.1
Bio-Rad Variant II Turbo 2.0	112	4.87	-0.22	3.2	6.88	-0.03	2.5	8.81	-0.03	2.2	10.02	0.04	2.5	5.35	-0.17	2.9
Bio-Rad Variant II	10	4.99	-0.10	3.8	6.86	-0.05	4.7	8.92	0.08	3.4	-	-	-	-	-	-
Roche cobas c311	21	5.06	-0.03	3.9	7.03	0.12	2.8	9.08	0.24	2.4	10.17	0.19	2.3	5.5	-0.02	1.7
Roche cobas c500 series	412	5.06	-0.03	2.6	6.99	0.08	2.4	8.95	0.11	2.4	10.04	0.06	2.4	5.5	-0.02	2.5
Roche cobas c513	63	5.17	0.08	2	7.03	0.12	1.9	9	0.16	2.1	10.11	0.13	1.8	5.58	0.06	1.4
Roche COBAS Integra 400	30	5.09	0.00	2	7.03	0.12	2.1	9.09	0.25	2.4	10.18	0.2	2.7	5.55	0.03	2.4
Sebia Capillarys 2 Flex Piercing	53	4.93	-0.16	2.6	6.74	-0.17	2.2	8.58	-0.26	2.4	9.73	-0.25	1.8	5.36	-0.16	3.1
Sebia Capillarys 3 (CAPI 3) Tera/Octa	32	4.99	-0.10	2.7	6.82	-0.09	2.7	8.72	-0.12	2.6	9.85	-0.13	1.7	5.4	-0.12	2.7
Siemens Atellica CH-Enzymatic reagent	114	4.97	-0.12	1.6	6.89	-0.02	1.5	8.93	0.09	1.6	10.1	0.12	1.5	5.4	-0.12	1.8
Siemens DCA Vantage	273	5.07	-0.02	2.8	6.95	0.04	2.7	8.9	0.06	3.1	9.91	-0.07	3.1	5.47	-0.05	2.3
Siemens Dimension ExL	174	5.14	0.05	2.4	6.88	-0.03	2.2	8.85	0.01	2.3	9.99	0.01	2.5	5.51	-0.01	2
Siemens Dimension Vista	142	5.13	0.04	2.2	6.74	-0.17	2	8.89	0.05	1.9	10.02	0.04	2.2	5.53	0.01	1.8
Tosoh G8 Automated HPLC	280	5.07	-0.02	1.6	7.08	0.17	1.4	9.08	0.24	1.3	10.19	0.21	1.2	5.59	0.07	1.6
Tosoh G11 Automated HPLC	10	5	-0.09	0.9	6.96	0.05	1	8.88	0.04	0.7	-	-	-	-	-	-
Trinity Biotech Premier Hb9210 HPLC	83	5.11	0.02	2.4	6.93	0.02	2.2	8.84	0.00	2	9.94	-0.04	2.2	5.52	0	2.5
Vitros 5,1 FS/4600/5600/XT 7600 Chem. Systems	211	5	-0.09	2.2	6.96	0.05	2.7	8.93	0.09	2.9	10.08	0.1	3.1	5.45	-0.07	2.1

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.
Green shading	samples GH5-11 and GH5-13 were hemolyzed; results for the Afinion are affected by this.

Figure 1: Bias and Variability from the NGSP Target




CAP GH5C 2022, 8.84% level (mean ± 2SD)
%HbA1c
10.5
10.0
9.5
9.0
8.5
8.0
7.5
7.0
6.5
NGSP Target ± 6%
Abbott Alinity ci series
Abbott Architect c System
ARKRAY Adams HA-8180 series
ARKRAY Adams HA-8180V
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 Turbo 2.0
Bio-Rad Variant II
Roche cobas c311
Roche cobas c500 series
Roche cobas c513
Roche COBAS Integra 400
Sebia Capillarys 2 Flex Piercing
Sebia Capillarys 3 (CAPI 3) Tera/Octa
Siemens Atellica CH- Enzymatic reagent
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;...

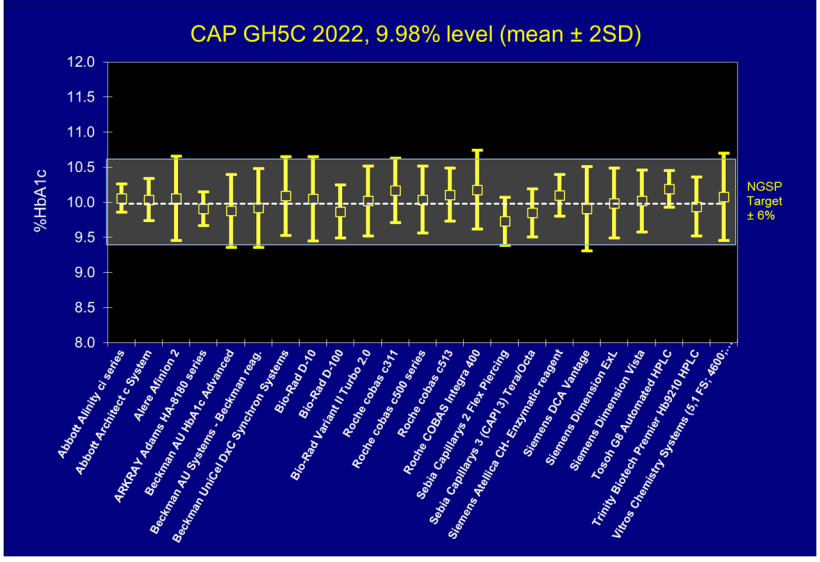

CAP GH5C 2022, 9.98% level (mean ± 2SD)
%HbA1c
12.0
11.5
11.0
10.5
10.0
9.5
9.0
8.5
8.0
NGSP Target ± 6%
Abbott Alinity ci series
Abbott Architect c System
Alere Afinion 2
ARKRAY Adams HA-8180 series
Beckman AU HbA1c Advanced
Beckman AU Systems - Beckman reag.
Beckman UniCel DxC Synchron Systems
Bio-Rad D-10
Bio-Rad D-100
Bio-Rad Variant II Turbo 2.0
Roche cobas c311
Roche cobas c500 series
Roche cobas c513
Roche COBAS Integra 400
Sebia Capillarys 2 Flex Piercing
Sebia Capillarys 3 (CAPI 3) Tera/Octa
Siemens Atellica CH- Enzymatic reagent
Siemens DCA Vantage
Siemens Dimension ExL
Siemens Dimension Vista
Tosoh G8 Automated HPLC
Trinity Biotech Premier Hb9210 HPLC
Vitros Chemistry Systems (5.1 FS; 4600;...

Table 2: Overall Variability for 2010-2022 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	6.4	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

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%.