

College of American Pathologists (CAP) GH5 Survey Data:

(updated 1/22)

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 2021 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 2021, based on data from the GH5-C survey:

- **Bias from the NGSP target and variability ($\pm 2SD$) 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 .**
- **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% (4.0%). The comments below will exclude sample GH-13.**
- **Bias:**
 - The absolute mean bias for each method group ranged from 0.00 to 0.34% HbA1c.
 - Only the Beckman AU Systems – Beckman reagent had one sample with a mean bias over 0.3% (0.34%) HbA1c.
- **Variability (CV)**
 - Method-specific, between-laboratory CVs ranged from 0.7% to 5.0%.
 - Two methods, Bio-Rad Variant II and Siemens DCA Vantage had CVs over 3.5% for 1/4 samples.
 - There were 10 methods with CVs $\leq 2\%$ for 4/4 or 2/2 (GH2) samples– the Abbott Alinity Ci series, Abbott Architect c, Arkray Adams HA-8180 series, Arkray Adams HA-8190V, Arkray The Lab 001, Roche cobas c513, Siemens Atellica CH- Enzymatic reagent, Siemens Dimension Vista, Tosoh G8, and Tosoh G11 Automated HPLC. This includes approximately 1/3 of participating laboratories with CVs $\leq 2\%$.
 - Over 85% of laboratories are using methods with between-lab CVs $\leq 3\%$ for 4/4 or 2/2 HbA1c levels.
- **Pass Rates**
 - The current pass limit for the GH5 survey is $\pm 6\%$. The overall pass rates in this survey were 98.4, 98.8, 98.0 and 97.2 for samples GH-11, 12, 14 and 15, respectively. 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 30 surveys are shown in Table 2. Overall CVs for the 4 samples in the current survey ranged from 2.4% to 2.7%.**

- 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.

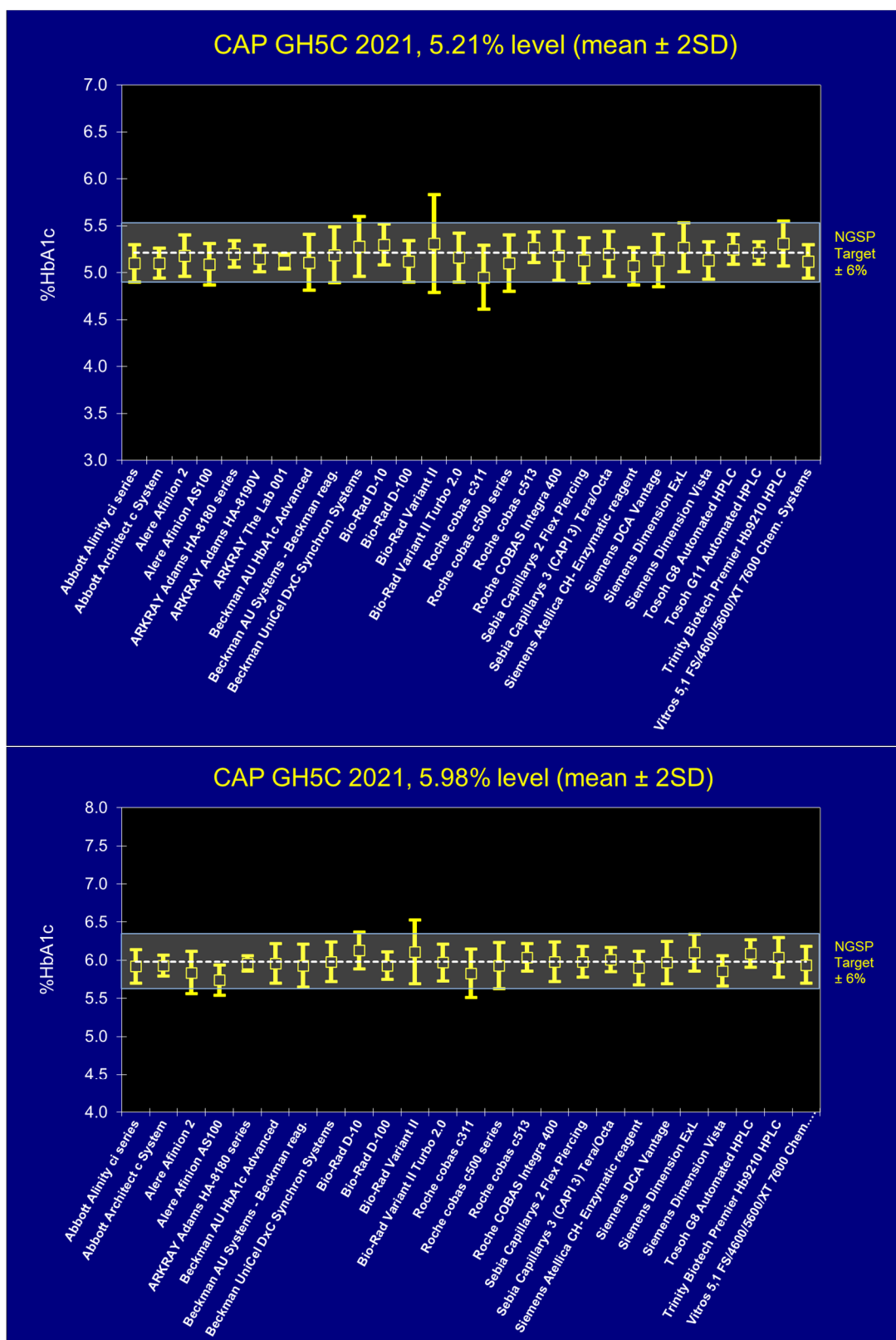
TABLE 1: 2021 GH5-C

		GH5-11			GH5-12			GH5-13			GH5-14			GH5-15		
NGSP %HbA1c Reference Value (95% CI)		5.21 (5.15-5.26)			6.68 (6.63-6.73)			GH-13 results showed an unusual amount of variability; no value was assigned			5.98 (5.93-6.03)			10.12 (10.07-10.18)		
Method name	no. labs	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	87	5.10	-0.11	2.0	6.59	-0.09	1.6	8.27		1.8	5.92	-0.06	1.9	10.40	0.28	1.7
Abbott Architect c System	225	5.10	-0.11	1.5	6.60	-0.08	1.3	8.26		1.7	5.93	-0.05	1.2	10.35	0.23	1.0
Alere Afinion 2	114	5.18	-0.03	2.2	6.59	-0.09	1.8	9.12		2.5	5.84	-0.14	2.3	10.11	-0.01	2.3
Alere Afinion AS100	88	5.09	-0.12	2.2	6.50	-0.18	2.2	9.07		3.0	5.74	-0.24	1.8	9.90	-0.22	1.9
ARKRAY Adams HA-8180 series	26	5.20	-0.01	1.4	6.69	0.01	1.3	8.28		1.4	5.96	-0.02	0.9	10.06	-0.06	0.8
ARKRAY Adams HA-8190V	25	5.15	-0.06	1.3	6.68	0.00	1.1	8.32		1.3	-	-	-	-	-	-
ARKRAY The Lab 001	13	5.12	-0.09	0.7	6.62	-0.06	1.4	8.29		2.5	-	-	-	-	-	-
Beckman AU HbA1c Advanced	27	5.11	-0.10	2.9	6.61	-0.07	2.4	8.06		3.8	5.96	-0.02	2.2	9.89	-0.23	1.8
Beckman AU Systems - Beckman reagent	66	5.19	-0.02	2.9	6.59	-0.09	3.2	8.11		3.1	5.93	-0.05	2.4	9.78	-0.34	3.4
Beckman UniCel Dx C Synchron Systems	65	5.28	0.07	3.1	6.66	-0.02	2.4	8.32		2.7	5.98	0.00	2.1	10.30	0.18	2.6
Bio-Rad D-10	112	5.30	0.09	2.2	6.82	0.14	1.9	8.49		2.4	6.13	0.15	1.9	10.25	0.13	1.9
Bio-Rad D-100	133	5.12	-0.09	2.1	6.66	-0.02	1.7	8.33		2.1	5.93	-0.05	1.5	9.99	-0.13	1.7
Bio-Rad Variant II	15	5.31	0.10	5.0	6.81	0.13	2.7	8.51		2.2	6.11	0.13	3.5	10.24	0.12	2.2
Bio-Rad Variant II Turbo 2.0	121	5.16	-0.05	2.4	6.74	0.06	1.8	8.43		2.2	5.97	-0.01	2.0	10.09	-0.03	1.5
Roche cobas c311	21	4.95	-0.26	3.4	6.53	-0.15	2.6	8.25		2.6	5.83	-0.15	2.7	10.21	0.09	2.2
Roche cobas c500 series	409	5.10	-0.11	2.9	6.63	0.05	2.2	8.25		2.4	5.93	-0.05	2.4	10.10	-0.02	2.6
Roche cobas c513	64	5.27	0.06	1.5	6.73	0.05	1.5	8.37		2.1	6.04	0.06	1.4	10.41	0.29	1.5
Roche COBAS Integra 400	32	5.18	-0.03	2.6	6.65	-0.03	2.6	8.50		2.2	5.98	0.00	2.2	10.31	0.19	2.2
Sebia Capillars 2 Flex Piercing	55	5.13	-0.08	2.3	6.70	0.02	1.7	8.05		1.6	5.98	0.00	1.7	10.03	-0.09	1.6
Sebia Capillars 3 (CAPI 3) Tera/Octa	26	5.20	-0.01	2.3	6.69	0.01	1.6	8.06		1.5	6.01	0.03	1.3	10.10	-0.02	1.2
Siemens Atellica CH- Enzymatic reagent	83	5.07	-0.14	2.0	6.55	-0.13	1.4	8.21		1.8	5.90	-0.08	1.8	10.27	0.15	1.2
Siemens DCA Vantage	306	5.13	-0.08	2.8	6.64	-0.04	2.6	8.26		3.3	5.97	-0.01	2.4	10.11	-0.01	3.7
Siemens Dimension ExL	185	5.27	0.06	2.5	6.70	0.02	1.9	8.18		1.8	6.10	0.12	1.9	9.92	-0.20	1.9
Siemens Dimension Vista	207	5.13	-0.08	1.9	6.50	-0.18	1.6	7.77		2.0	5.86	-0.12	1.8	9.99	-0.13	1.7
Tosoh G8 Automated HPLC	304	5.25	0.04	1.6	6.84	0.16	1.4	8.52		2.3	6.09	0.11	1.4	10.26	0.14	1.6
Tosoh G11 Automated HPLC	10	5.21	0.00	1.1	6.75	0.07	1.4	8.36		2.3	-	-	-	-	-	-
Trinity Biotech Premier Hb9210 HPLC	81	5.31	0.10	2.2	6.74	0.06	2.0	8.50		2.4	6.04	0.06	2.1	10.30	0.18	1.9
Vitros 5,1 FS/4600/5600/XT 7600 Chem. Systems	199	5.12	-0.09	1.9	6.67	-0.01	2.4	8.22		2.6	5.94	-0.04	2.1	10.15	0.03	3.2

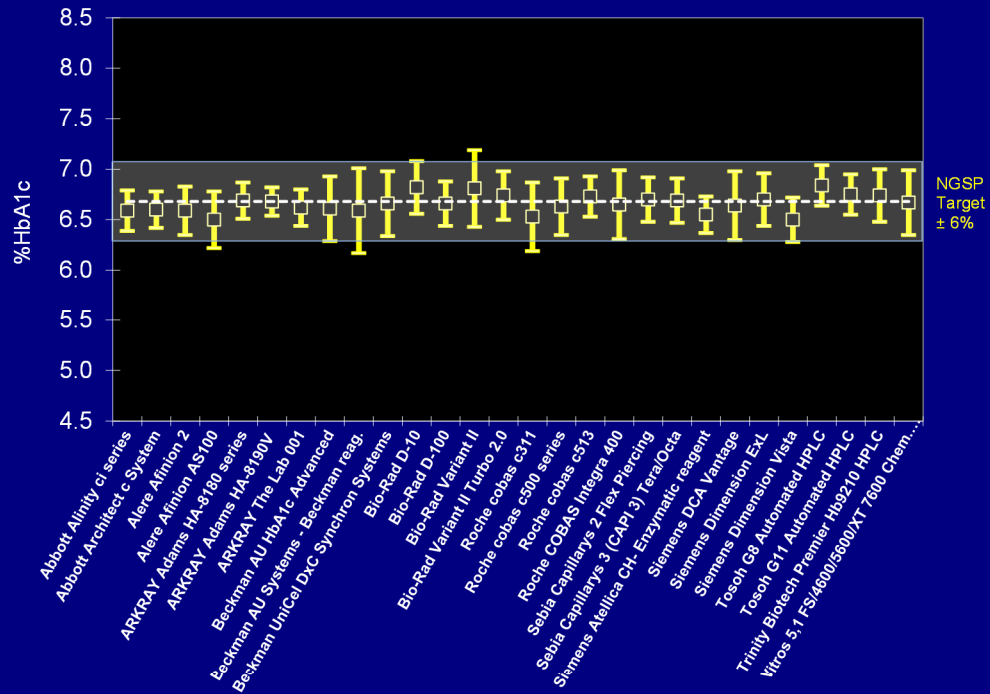
Gray shading

indicates bias > 0.3% HbA1c or CV > 3.5% 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 2021, 6.68% level (mean $\pm$ 2SD)



CAP GH5C 2021, 10.12% level (mean $\pm$ 2SD)

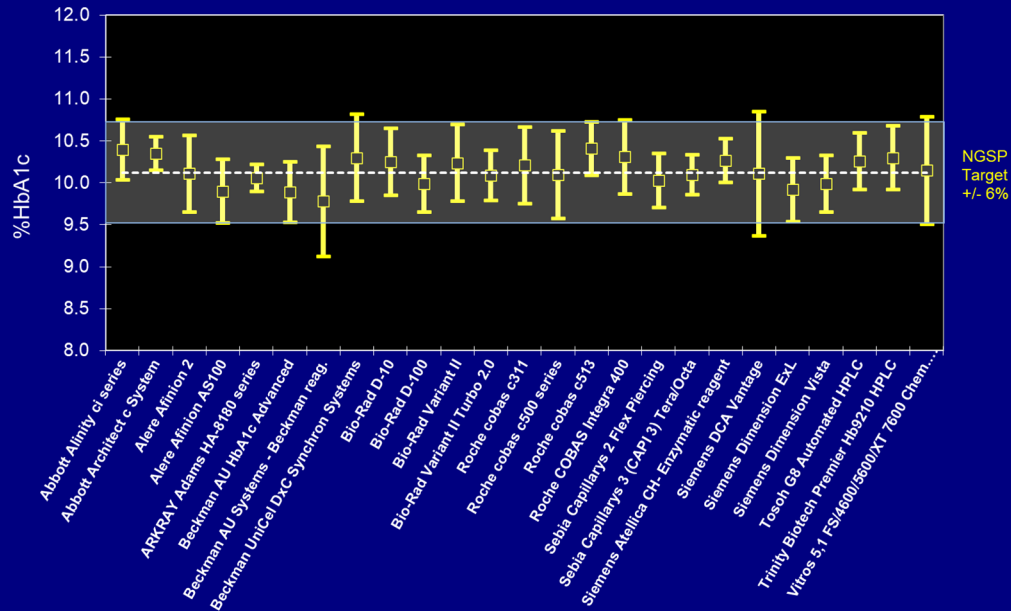


Table 2: Overall Variability for 2010-2021 for all GH participants

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

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%.