

College of American Pathologists (CAP) GH5 Survey Data:

(updated 6/19)

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 **first** survey of 2019 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 2019, based on data from the GH5-A 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 .
- Sample GH5-02 contained HbS (HbAS). Comments about this sample are listed separately in the last bullet.
- For samples containing only HbAA, the absolute mean bias for each method group ranged from zero to 0.40% HbA1c. There were two methods with a bias $> 0.30\%$ HbA1c (Siemens Dimension Vista and Dimension Xpand).
- Method-specific, between-laboratory CV's ranged from 0.9% to 4.5%. The Beckman AU and Siemens Dimension ExL had CVs over 3.5% for 2/4 samples. The Roche Cobas Integra 400 had a CV over 3.5% for 1/4 samples. There were four methods with CVs $\leq 2\%$ for 4/4 samples– the Abbott Architect c enzymatic, Arkray Adams HA-8180, Roche cobas c513 and Tosoh G8. Only 45% of laboratories are using methods with between-lab CVs $\leq 3\%$ at all four HbA1c levels; approximately 91% of laboratories are using methods with CVs $\leq 3.5\%$ at all four HbA1c levels.
- The current pass limit for the GH5 survey is $\pm 6\%$. The overall pass rates for the AA samples in this survey were 94.0%, 96.0%, 96.3% and 97.9 for GH5-01, 03, 04 and 05, respectively. For individual methods, the lowest pass rate was 80% and the highest was 100%. The overall pass rates with a pass limit of 5% were 92.9% to 96.1%. 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 CVs for the last 21 surveys are shown in Table 2. The overall CV for GH5-01 was quite high (3.6%). The other CVs were in line with what we have seen for the last few surveys (2.7-3.3%).
- Laboratories should avoid using methods with high CVs and consistent high bias.
- Concerning sample GH5-02 (HbAS): The overall CV for this sample was higher than for samples without a Hb variant (4.4%) and the cumulative pass rate for this sample was lower (87%). A few methods showed more of a bias than expected compared to sample GH-01 (AA with comparable HbA1c) and based on previous variant interference studies.

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

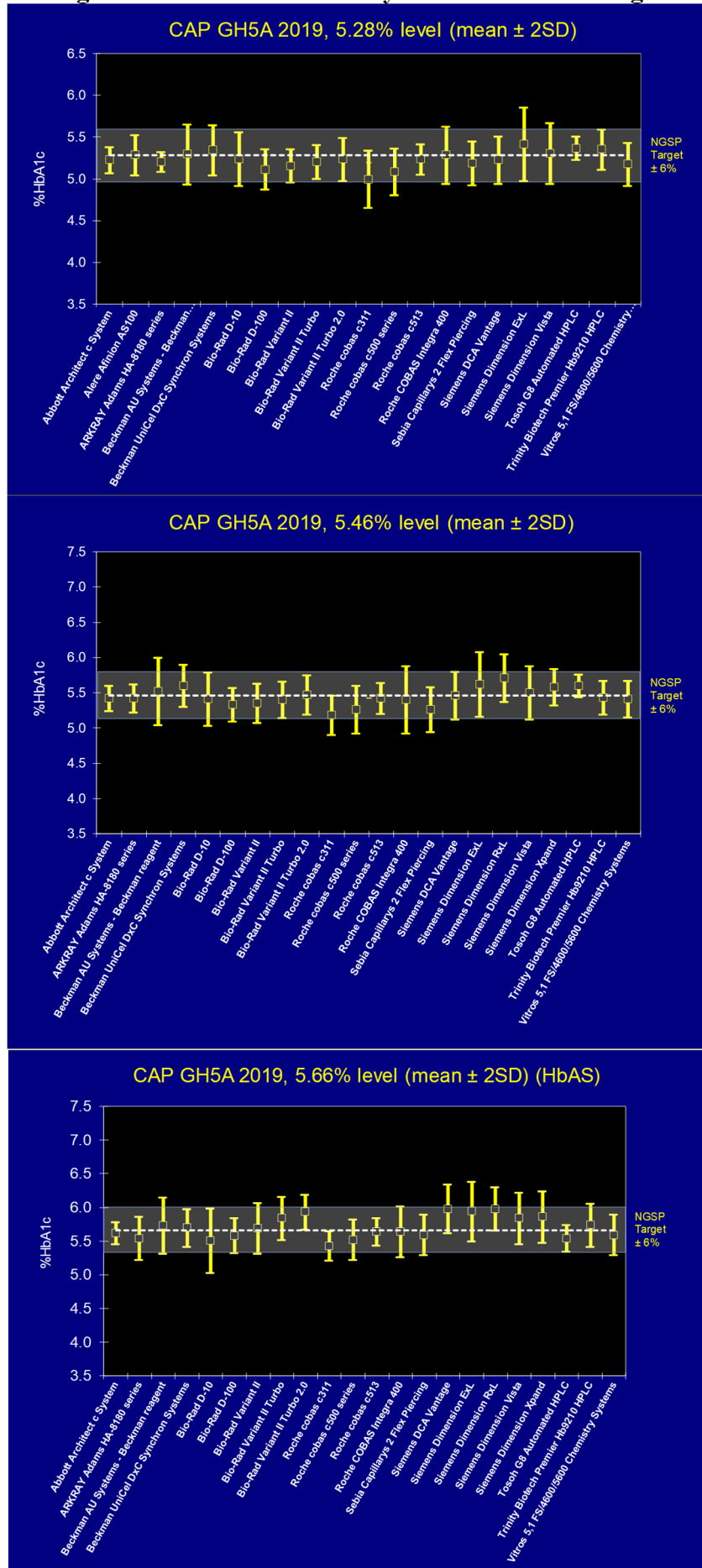
reflects between-laboratory reproducibility, often with more than one lot of reagents and calibrators, and sometimes with different instruments (e.g. Siemens Advia instruments) and/or different applications (e.g. with or without sample pretreatment). In addition, if changes were made in the method just 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: 2019 GH5-A

		GH5-01			GH5-02 (HbAS)			GH5-03			GH5-04			GH5-05		
NGSP %HbA1c Reference Value (95% CI)		5.46 (5.42-5.50)			5.66 (5.61-5.70)			9.31 (9.26-9.35)			5.28 (5.24-5.32)			7.41 (7.37-7.45)		
	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 Architect c System	233	5.42	-0.04	1.6	5.62	-0.04	1.5	9.39	0.08	1.8	5.22	-0.06	1.6	7.40	-0.01	1.6
Alere Afinion A S100	97							9.24	-0.07	1.3	5.28	0.00	2.2	7.28	-0.13	1.5
Alere Afinion 2	12							9.15	-0.16	2.0						
ARKRAY Adams HA-8180 series	17	5.42	-0.04	1.8	5.54	-0.12	2.9	9.41	0.10	1.7	5.20	-0.08	1.2	7.43	0.02	0.9
Beckman AU Systems - Beckman reagent	87	5.52	0.06	4.3	5.73	0.07	3.7	9.01	-0.30	3.5	5.29	0.01	3.3	7.34	-0.07	3.8
Beckman UniCel DxC Synchron Systems	84	5.60	0.14	2.7	5.70	0.04	2.5	9.39	0.08	2.7	5.34	0.06	2.9	7.32	-0.09	2.8
Bio-Rad D-10	155	5.41	-0.05	3.5	5.51	-0.15	4.4	9.49	0.18	2.3	5.23	-0.05	3.0	7.54	0.13	2.2
Bio-Rad D-100	102	5.33	-0.13	2.2	5.58	-0.08	2.4	9.11	-0.20	1.7	5.11	-0.17	2.4	7.23	-0.18	2
Bio-Rad Variant II	22	5.35	-0.11	2.6	5.69	0.03	3.4	9.47	0.16	2.0	5.15	-0.13	2.0	7.45	0.04	1.9
Bio-Rad Variant II Turbo	42	5.40	-0.06	2.5	5.84	0.18	2.7	9.45	0.14	1.7	5.20	-0.08	2.0	7.50	0.09	1.8
Bio-Rad Variant II Turbo 2.0	120	5.47	0.01	2.5	5.93	0.27	2.3	9.48	0.17	1.6	5.23	-0.05	2.6	7.51	0.10	1.9
Roche cobas c311	19	5.18	-0.28	2.7	5.43	-0.23	1.9	9.33	0.02	1.2	4.99	-0.29	3.3	7.31	-0.10	1.1
Roche cobas c500 series	416	5.26	-0.20	3.2	5.52	-0.14	2.8	9.20	-0.11	2.4	5.08	-0.20	2.8	7.34	-0.07	2.2
Roche cobas c513	63	5.42	-0.04	1.9	5.64	-0.02	1.8	9.53	0.22	1.8	5.23	-0.05	1.8	7.45	0.04	1.6
Roche COBAS Integra 400	44	5.40	-0.06	4.5	5.64	-0.02	3.4	9.32	0.01	2.6	5.28	0.00	3.3	7.35	-0.06	3.3
Sebia Capillars 2 Flex Piercing	73	5.26	-0.20	3.1	5.59	-0.07	2.8	9.28	-0.03	1.3	5.18	-0.10	2.4	7.33	-0.08	1.4
Siemens DCA Vantage	392	5.46	0.00	3.0	5.98	0.32	2.9	9.36	0.05	3.3	5.22	-0.06	2.6	7.40	-0.01	2.5
Siemens Dimension ExL	214	5.62	0.16	4.1	5.94	0.28	3.7	9.03	-0.28	2.2	5.41	0.13	4.0	7.43	0.02	2.9
Siemens Dimension RxL	10	5.71	0.25	3.0	5.98	0.32	2.7	9.06	-0.25	2.0						
Siemens Dimension Vista	290	5.50	0.04	3.5	5.84	0.18	3.3	8.91	-0.40	2.3	5.30	0.02	3.4	7.55	0.14	2.5
Siemens Dimension Xpand	15	5.58	0.12	2.4	5.86	0.20	3.3	9.00	-0.31	3.3						
Tosoh G8 Automated HPLC	347	5.60	0.14	1.4	5.54	-0.12	1.7	9.55	0.24	1.3	5.36	0.08	1.4	7.60	0.19	1.3
Trinity Biotech Premier Hb9210 HPLC	89	5.43	-0.03	2.2	5.74	0.08	2.8	9.43	0.12	2.0	5.35	0.07	2.2	7.45	0.04	2.2
Vitros 5,1 FS/4600/5600 Chemistry Systems	193	5.41	-0.05	2.5	5.59	-0.07	2.7	9.36	0.05	2.7	5.17	-0.11	2.4	7.31	-0.10	2.9

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



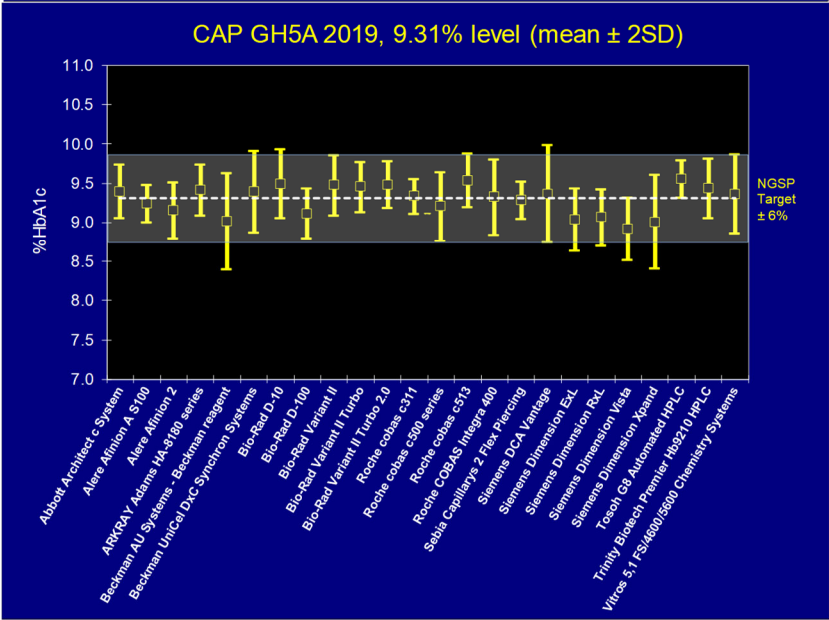
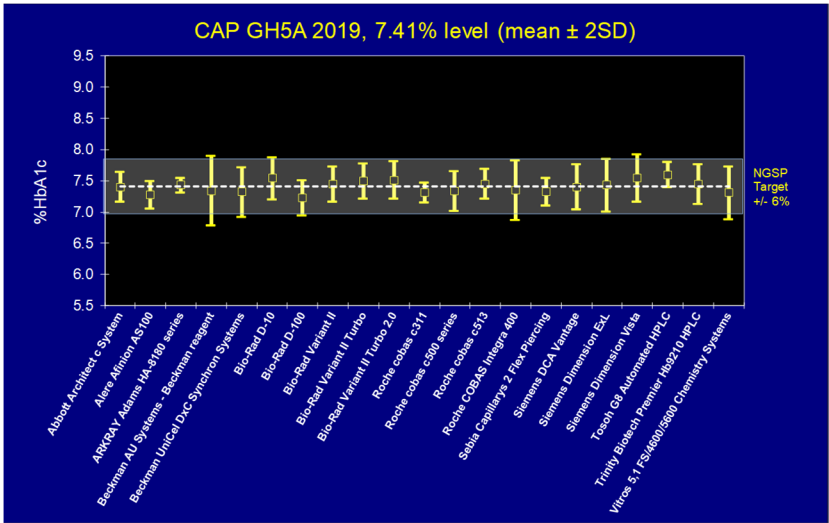


Table 2: Overall Variability for 2010-2018 for all GH participants

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

CVs **below** 3.5% are highlighted in pink
CVs **below** 3.0% are highlighted in blue
HbAS samples is indicated in yellow