

College of American Pathologists (CAP) GH5 Survey Data:

(updated 12/16)

The American Diabetes Association (ADA) recommends that laboratories use only HbA1c assay methods that have been NGSP certified and report results as “%HbA1c”. The ADA also recommends that all laboratories performing HbA1c testing participate in the College of American Pathologists (CAP) fresh sample proficiency testing survey (see ADA Recommendations section on this website for more details). CAP GH5 data for the **third** survey of 2016 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 2016, 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 (ordered by HbA1c level in figure) for each method. The shaded rectangle (fig 1) reflects the current CAP acceptance limit of ± 6 . Method-specific biases > 0.30 (shaded cells, table) were only seen in the highest level sample. For the 11.71% HbA1c sample 6 methods showed > 0.30 bias (Architect i, Biomajesty, DCA2000, Dimension ExL, Dimension Vista and Vitros).
- Method-specific, between-laboratory CV's ranged from 0.5% to 6.3%. The Abbott Architect i immunoassay again had high CVs (over 5% for all 3 samples for which CVs were calculated) and the Beckman AU had CVs over 3.5% for all five samples. There were only two methods with CVs $\leq 2\%$ for 5/5 samples – the Abbott Architect c enzymatic and the Tosoh G8. The Arkray HA-8180 had CVs $< 2\%$ for the 3 samples for which CVs were calculated. Approximately 60% of laboratories are using methods with between-lab CVs $\leq 3\%$ at all five HbA1c levels; approximately 78% of laboratories are using methods with CVs $\leq 3.5\%$ at all five HbA1c levels.
- The current pass limit for the GH5 survey is $\pm 6\%$. The overall pass rates for this survey were 96.6%, 97.4%, 93.5%, 97.1% and 98.1% for GH5-11 through 15, respectively. For individual methods, the lowest pass rate was 54.5% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH5-C 2016). 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 14 surveys are shown in Table 2. CVs were $< 3.5\%$ for all samples in the current survey.

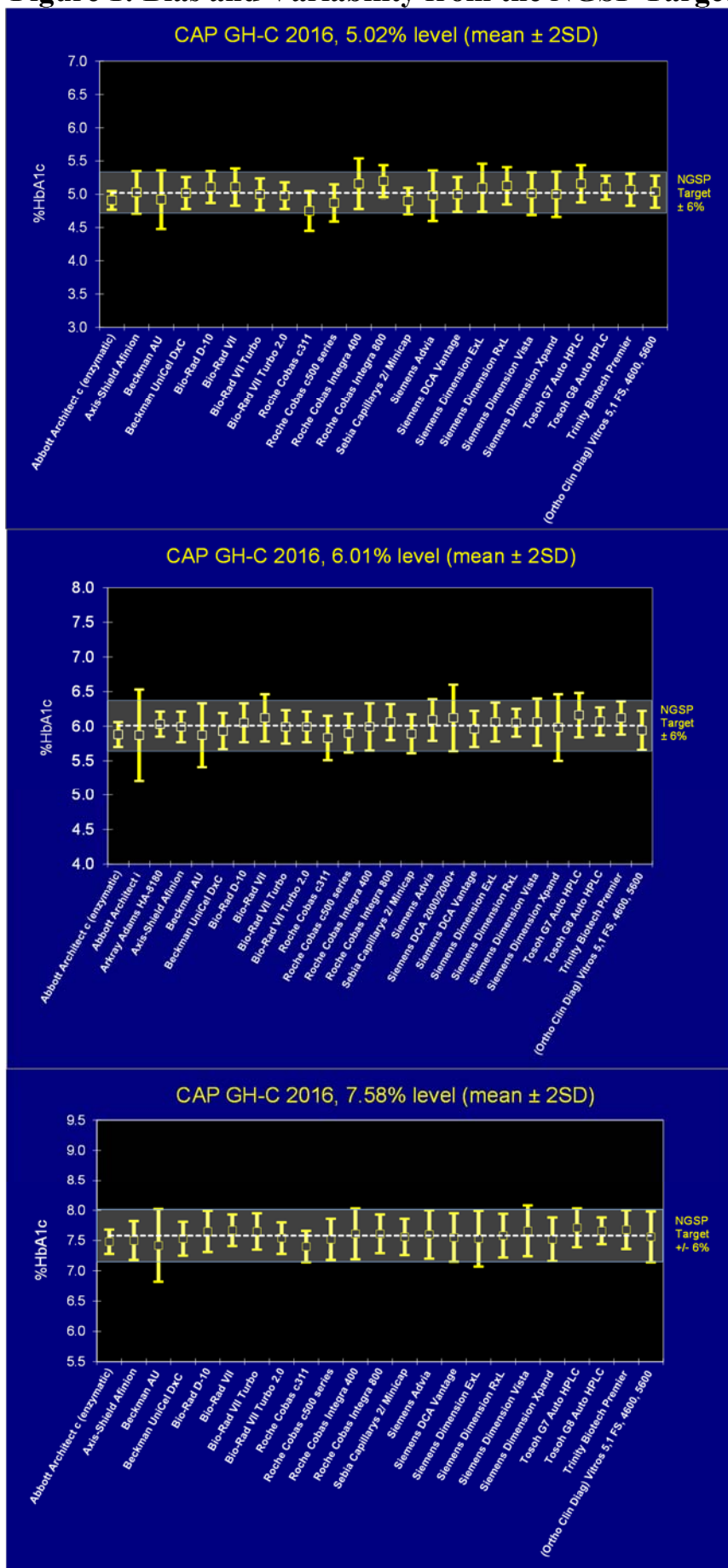
NOTE: The NGSP certification evaluates agreement of each method at the manufacturing site using one lot of reagents and calibrators, one instrument, and one application under optimal conditions. CAP precision reflects between-laboratory reproducibility, often with more than one lot of reagents and calibrators, and sometimes with different instruments (e.g. Cobas Integra 400 & Cobas Integra 800) and/or different applications (e.g. Cobas Integra hemolysate or whole blood application). 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: 2016 GH5-C (fresh pooled samples)

		GH5-11			GH5-12			GH5-13			GH5-14			GH5-15		
[†] NGSP %HbA1c Reference Value (95% CI)		9.11 (9.04-9.17)			6.01 (5.95-6.07)			11.71 (11.63-11.78)			5.02 (4.96-5.08)			7.58 (7.52-7.64)		
	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 (enzymatic)	109-132	9.04	-0.07	1.6	5.88	-0.13	1.6	11.75	0.04	1.3	4.91	-0.11	1.5	7.48	-0.10	1.4
Abbott Architect i	8-11	8.93	-0.18	5.4	5.87	-0.14	5.5	11.09	-0.62	6.3						
Arkray Adams HA-8180	0-17	9.18	0.07	0.5	6.03	0.02	1.5	11.81	0.10	1.1						
Axis-Shield Afinion	15-82	8.97	-0.14	1.4	5.99	-0.02	1.9	11.65	-0.06	2.0	5.03	0.01	3.1	7.50	-0.08	2.2
Beckman AU	57-89	8.98	-0.13	4.0	5.87	-0.14	3.9	11.60	-0.11	4.6	4.92	-0.10	4.5	7.42	-0.16	4.0
Beckman UniCel DxC	101-133	9.21	0.10	2.4	5.93	-0.08	2.2	11.83	0.12	2.6	5.02	0.00	2.4	7.53	-0.05	1.9
Bio-Rad D-10	125-172	9.16	0.05	2.5	6.05	0.04	2.4	11.85	0.14	2.6	5.11	0.09	2.3	7.65	0.07	2.2
Bio-Rad VII	44-53	9.23	0.12	2.2	6.12	0.11	2.7	11.91	0.20	2.3	5.11	0.09	2.8	7.67	0.09	1.7
Bio-Rad VII Turbo	77-84	9.16	0.05	2.4	5.99	-0.02	2.1	11.73	0.02	2.8	5.00	-0.02	2.3	7.65	0.07	2.0
Bio-Rad VII Turbo 2.0	147-173	9.13	0.02	2.0	5.99	-0.02	1.8	11.49	-0.22	2.0	4.98	-0.04	2.0	7.54	-0.04	1.7
JEOL Biomajesty JCA-BM series	7-10	8.97	-0.14	1.8				12.02	0.31	1.7						
Roche Cobas c311	16-28	9.15	0.04	2.3	5.83	-0.18	2.8	11.52	-0.19	2.0	4.75	-0.27	3.1	7.40	-0.18	1.8
Roche Cobas c500 series	331-399	9.03	-0.08	2.2	5.90	-0.11	2.3	11.43	-0.28	2.6	4.87	-0.15	2.9	7.52	-0.06	2.2
Roche Cobas Integra 400	30-60	9.16	0.05	3.1	5.99	-0.02	2.8	11.64	-0.07	3.5	5.16	0.14	3.6	7.61	0.03	2.8
Roche Cobas Integra 800	104-118	9.14	0.03	2.3	6.06	0.05	2.1	11.81	0.10	1.9	5.20	0.18	2.3	7.61	0.03	2.1
Sebia Capillarys 2/ Minicap	28-43	9.02	-0.09	1.5	5.89	-0.12	2.3	11.53	-0.18	1.8	4.90	-0.12	2.0	7.56	-0.02	2.0
Siemens Advia	21-24	9.08	-0.03	2.3	6.09	0.08	2.5	11.42	-0.29	3.0	4.98	-0.04	3.8	7.60	0.02	2.6
Siemens DCA 2000/2000+	5-21	9.22	0.11	3.4	6.12	0.11	4.0	12.17	0.46	3.6						
Siemens DCA Vantage	176-460	9.05	-0.06	2.6	5.96	-0.05	2.2	11.92	0.21	4.3	5.00	-0.02	2.5	7.55	-0.03	2.6
Siemens Dimension ExL	142-209	9.02	-0.09	2.5	6.06	0.05	2.3	11.39	-0.32	2.3	5.10	0.08	3.4	7.53	-0.05	3.1
Siemens Dimension RxL	14-22	9.02	-0.09	1.6	6.05	0.04	1.7	11.42	-0.29	2.1	5.13	0.11	2.8	7.58	0.00	2.4
Siemens Dimension Vista	260-291	8.86	-0.25	2.5	6.06	0.05	2.8	11.39	-0.32	2.2	5.01	-0.01	3.1	7.66	0.08	2.7
Siemens Dimension Xpand	17-36	9.04	-0.07	2.5	5.98	-0.03	4.0	11.43	-0.28	2.5	5.00	-0.02	3.5	7.52	-0.06	2.4
Tosoh G7 Auto HPLC	13-21	9.24	0.13	1.8	6.16	0.15	2.6	11.82	0.11	1.8	5.16	0.14	2.8	7.71	0.13	2.1
Tosoh G8 Auto HPLC	321-373	9.17	0.06	1.6	6.07	0.06	1.6	11.73	0.02	1.5	5.10	0.08	1.7	7.66	0.08	1.4
Trinity Biotech Premier	58-69	9.20	0.09	2.2	6.12	0.11	2.0	11.99	0.28	2.1	5.07	0.05	2.3	7.68	0.10	2.1
(Ortho Clin Diag) Vitros 5,1 FS, 4600, 5600	155-190	9.25	0.14	2.7	5.94	-0.07	2.3	12.11	0.40	2.9	5.04	0.02	2.4	7.56	-0.02	2.8

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



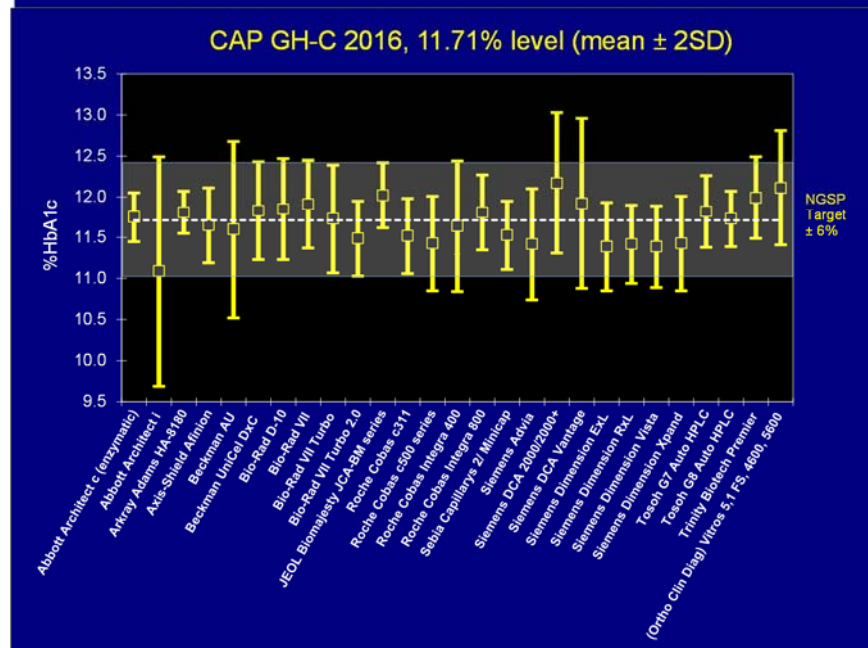
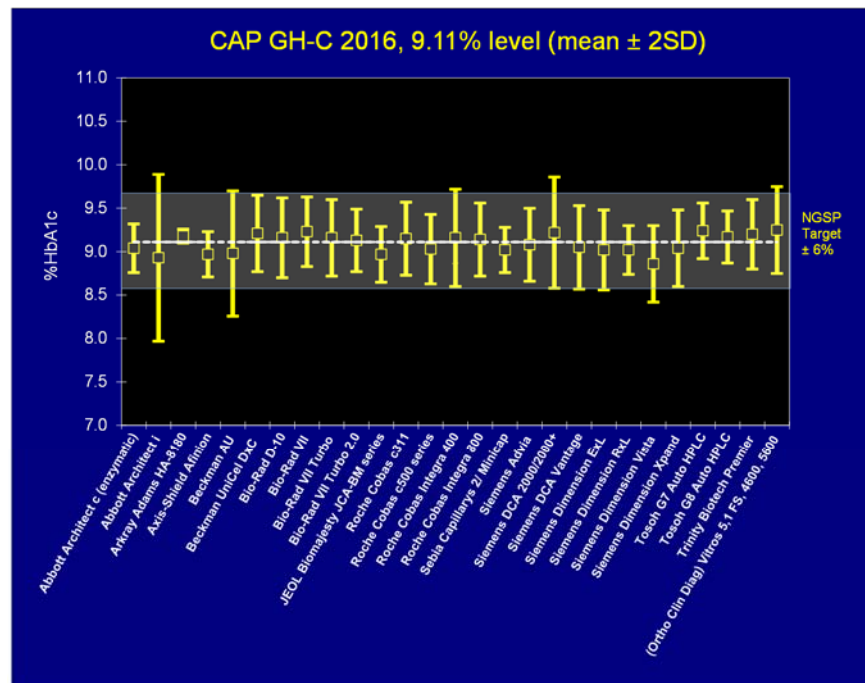


Table 2: Overall Variability for 2010-2016 for all GH participants

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 (HbAS)	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	0.20	3.5
	07	2392	11.71	11.68	0.44	3.8
	08	2402	9.53	9.50	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	5.20	0.17	3.3
	14	2410	8.14	8.12	0.24	2.9
	15	2408	9.30	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

CVs below 3.5% are highlighted in pink