College of American Pathologists (CAP) GH5 Survey Data:

(updated 8/15)

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 **second** survey of 2015 are summarized below. The NGSP target or reference values are based on replicate analyses using seven 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 will be shipped twice a year with three samples in each mailing as before. GH5 will be shipped three times a year with five samples in each mailing. The three samples in each of the two GH2 mailings will also be 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 2015, based on data from the GH5-B survey:

- **Bias from the NGSP target and variability (±2SD) are shown in Table 1 and in figure 1 (ordered by HbA1c level) for each method. The shaded rectangle (fig 1) reflects the current CAP acceptance limit of ±6. The method-specific biases were > 0.30 (shaded cells) for two of the 5 HbA1c samples for the Bio-Rad Variant II and Ortho Clinical Diagnostics Vitros methods. The Abbott Architect c immunoassay, Roche Cobas c500 series and Integra 400, Siemens DCA Vantage, Advia, Dimension RxL and ExL, and Trinity Biotech HPLC had bias >0.30 for 1 sample. All biases for the remaining methods were ≤0.3%**
- **Method-specific, between-laboratory CV's ranged from 1.5% to 8.6%. The Abbott Architect i immunoassay had CVs over 6% for all samples and the Siemens Advia had CVs over 4% (shaded cells) for four out of five samples. Three additional methods each had one CV >4% (Abbott Architect c immunoassay, Beckman AU, Siemens DCA Vantage). The lowest CVs, ≤2% for 5/5 samples, were seen with the Tosoh G8 and G7. Good precision (CVs≤2% for 3/5 samples) was also seen with the Abbott Architect c (enzymatic), Axis-Shield Afinion, Sebia Capillarys and Trinity Biotech HPLC. Approximately 43% of laboratories are using methods with CVs ≤3% at all five HbA1c levels; approximately 78% of laboratories are using methods with CVs ≤3.5% at all five HbA1c levels.**
- **The current pass limit for the GH2 survey is ±6%. The overall pass rates for this survey were 94.8, 91.0, 94.6, 95.6, and 94.9% for GH5-06 through 10, respectively. For individual methods, the lowest pass rate was 57.1% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH5-B 2015). 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 12 surveys are shown in Table 2. We are still hovering around our goal of ≤3.5%.**

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.

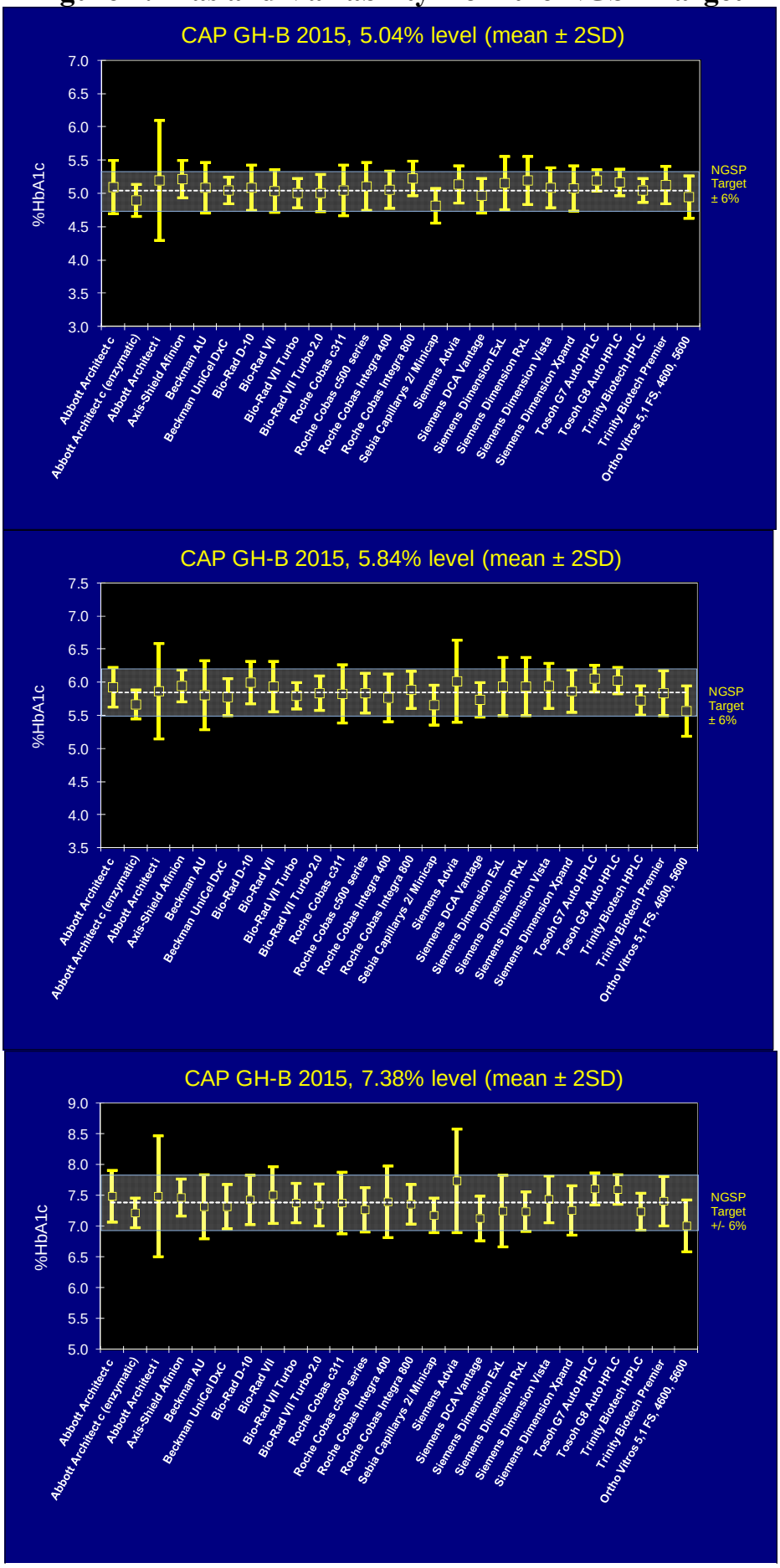
TABLE 1: 2015 GH5-B (fresh pooled samples)

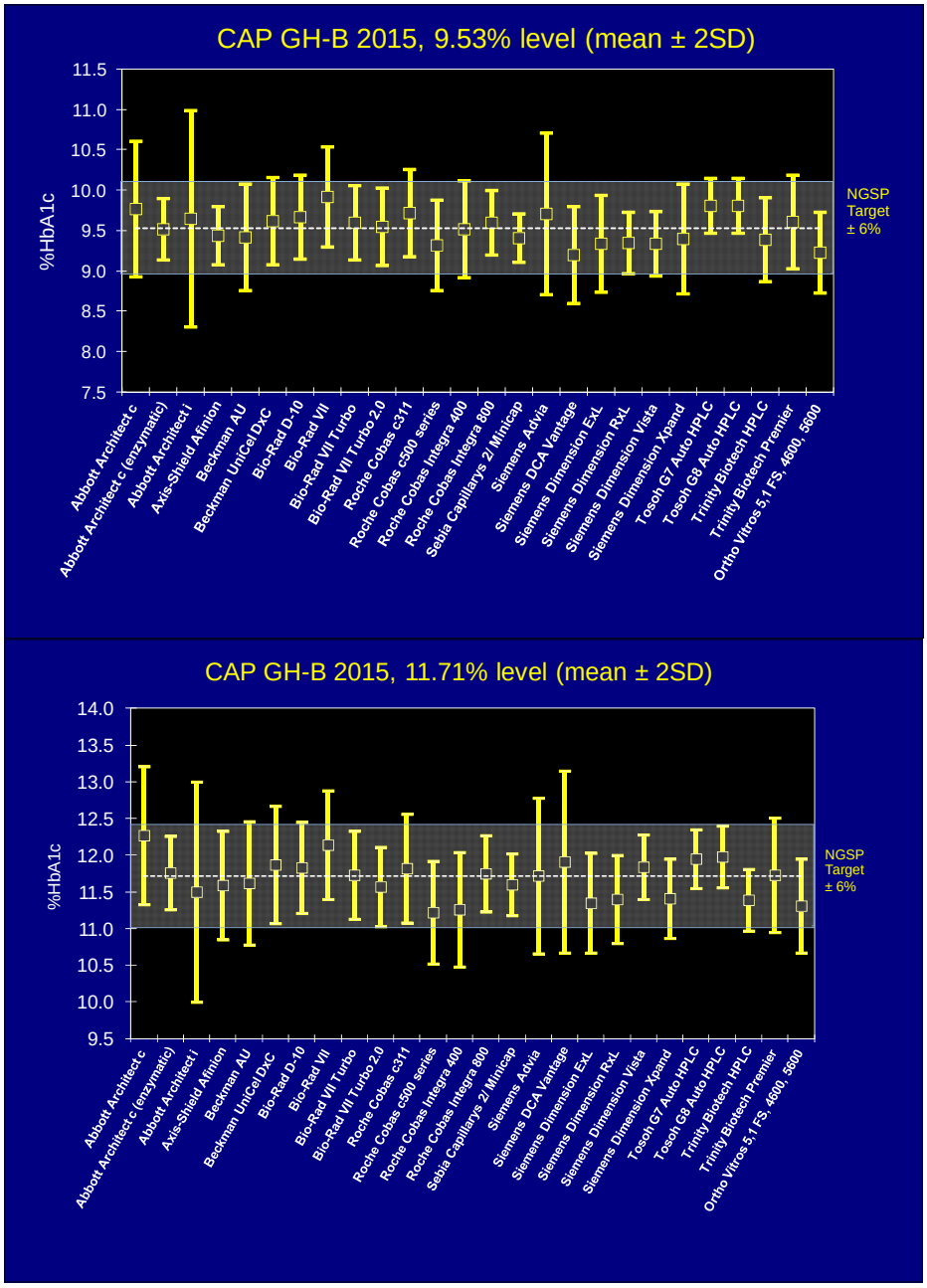
		GH5-06			GH5-07			GH5-08			GH5-09			GH5-10		
[t] NGSP %HbA1c Reference Value (95% CI)		5.84 (5.74-5.93)			11.71 (11.61-11.80)			9.53 (9.44-9.62)			5.04 (4.95-5.13)			7.38 (7.29-7.47)		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
Abbott Architect c	24	5.93	0.09	2.6	12.27	0.56	3.8	9.77	0.24	4.3	5.10	0.06	3.9	7.49	0.11	2.8
Abbott Architect c (enzymatic)	47	5.67	-0.17	2.0	11.76	0.05	2.1	9.52	-0.01	2.0	4.90	-0.14	2.4	7.22	-0.16	1.7
Abbott Architect i	21	5.87	0.03	6.2	11.50	-0.21	6.5	9.65	0.12	7.0	5.20	0.16	8.6	7.49	0.11	6.6
Axis-Shield Afinion	19	5.95	0.11	2.0	11.59	-0.12	3.2	9.44	-0.09	1.9	5.22	0.18	2.8	7.47	0.09	2.0
Beckman AU	42	5.81	-0.03	4.5	11.62	-0.09	3.6	9.42	-0.11	3.5	5.09	0.05	3.7	7.32	-0.06	3.6
Beckman UniCel DxC	117	5.78	-0.06	2.4	11.87	0.16	3.3	9.62	0.09	2.8	5.05	0.01	2.0	7.32	-0.06	2.5
Bio-Rad D-10	133	6.00	0.16	2.7	11.83	0.12	2.6	9.67	0.14	2.7	5.09	0.05	3.3	7.43	0.05	2.6
Bio-Rad VII	60	5.94	0.10	3.2	12.14	0.43	3.1	9.92	0.39	3.1	5.04	0.00	3.2	7.51	0.13	3.1
Bio-Rad VII Turbo	82	5.80	-0.04	1.7	11.73	0.02	2.5	9.60	0.07	2.4	5.01	-0.03	2.3	7.38	0.00	2.1
Bio-Rad VII Turbo 2.0	132	5.84	0.00	2.3	11.57	-0.14	2.3	9.55	0.02	2.5	5.01	-0.03	2.7	7.35	-0.03	2.3
Roche Cobas c311	18	5.83	-0.01	3.8	11.82	0.11	3.1	9.72	0.19	2.7	5.05	0.01	3.8	7.38	0.00	3.4
Roche Cobas c500 series	294	5.84	0.00	2.7	11.22	-0.49	3.2	9.32	-0.21	3.1	5.11	0.07	3.5	7.27	-0.11	2.4
Roche Cobas Integra 400	26	5.77	-0.07	3.2	11.26	-0.45	3.4	9.52	-0.01	3.1	5.06	0.02	2.8	7.40	0.02	3.9
Roche Cobas Integra 800	108	5.89	0.05	2.4	11.75	0.04	2.2	9.60	0.07	2.1	5.23	0.19	2.4	7.36	-0.02	2.2
Sebia Capillarys 2/ Minicap	17	5.66	-0.18	2.7	11.60	-0.11	1.8	9.41	-0.12	1.5	4.82	-0.22	2.8	7.18	-0.20	1.9
Siemens Advia	24	6.02	0.18	5.1	11.72	0.01	4.5	9.71	0.18	5.2	5.14	0.10	2.7	7.74	0.36	5.5
Siemens DCA Vantage	168	5.74	-0.10	2.3	11.91	0.20	5.2	9.20	-0.33	3.2	4.97	-0.07	2.7	7.13	-0.25	2.6
Siemens Dimension ExL	126	5.94	0.10	3.7	11.35	-0.36	3.0	9.34	-0.19	3.2	5.16	0.12	4.0	7.25	-0.13	4.0
Siemens Dimension RxL	25	5.94	0.10	3.8	11.40	-0.31	2.7	9.35	-0.18	2.1	5.20	0.16	3.5	7.24	-0.14	2.2
Siemens Dimension Vista	251	5.95	0.11	2.8	11.84	0.13	1.9	9.34	-0.19	2.2	5.09	0.05	3.0	7.44	0.06	2.5
Siemens Dimension Xpand	22	5.87	0.03	2.8	11.41	-0.30	2.3	9.40	-0.13	3.7	5.08	0.04	3.3	7.26	-0.12	2.8
Tosoh G7 Auto HPLC	50	6.06	0.22	1.6	11.95	0.24	1.7	9.81	0.28	1.8	5.20	0.16	1.6	7.61	0.23	1.6
Tosoh G8 Auto HPLC	285	6.03	0.19	1.7	11.98	0.27	1.7	9.81	0.28	1.7	5.17	0.13	2.0	7.60	0.22	1.5
Trinity Biotech HPLC	14	5.73	-0.11	1.9	11.39	-0.32	1.9	9.39	-0.14	2.7	5.05	0.01	1.9	7.24	-0.14	2.1
Trinity Biotech Premier	53	5.84	0.00	2.9	11.73	0.02	3.3	9.61	0.08	3.0	5.13	0.09	2.7	7.41	0.03	2.7
(Ortho Clin Diag) Vitros 5,1 FS, 4600, 5600	154	5.57	-0.27	3.5	11.31	-0.40	2.8	9.23	-0.30	2.7	4.95	-0.09	3.2	7.01	-0.37	3.1

[t] Assigned as the mean of 3 replicate analyses per day for two days per method using 6 NGSP certified secondary reference methods.

Gray shading indicates bias > 0.3% HbA1c or CV > 4% 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 GH-B 2015, 9.53% level (mean ± 2SD)
%HbA1c
11.5
11.0
10.5
10.0
9.5
9.0
8.5
8.0
7.5
NGSP Target ± 6%
Abbott Architect c
Abbott Architect c (enzymatic)
Abbott Architect i
Axis-Shield Afinion
Beckman AU
Beckman UniCel DxC
Bio-Rad D-10
Bio-Rad VII
Bio-Rad VII Turbo
Bio-Rad VII Turbo 2.0
Roche Cobas c311
Roche Cobas c500 series
Roche Cobas Integra 400
Roche Cobas Integra 800
Sebia Capillarys 2/ Minicap
Siemens Advia
Siemens DCA Vantage
Siemens Dimension ExL
Siemens Dimension RxL
Siemens Dimension Vista
Siemens Dimension Xpand
Tosoh G7 Auto HPLC
Tosoh G8 Auto HPLC
Trinity Biotech HPLC
Trinity Biotech Premier
Ortho Vitros 5,1 FS, 4600, 5600

CAP GH-B 2015, 11.71% level (mean ± 2SD)
%HbA1c
14.0
13.5
13.0
12.5
12.0
11.5
11.0
10.5
10.0
9.5
NGSP Target ± 6%
Abbott Architect c
Abbott Architect c (enzymatic)
Abbott Architect i
Axis-Shield Afinion
Beckman AU
Beckman UniCel DxC
Bio-Rad D-10
Bio-Rad VII
Bio-Rad VII Turbo
Bio-Rad VII Turbo 2.0
Roche Cobas c311
Roche Cobas c500 series
Roche Cobas Integra 400
Roche Cobas Integra 800
Sebia Capillarys 2/ Minicap
Siemens Advia
Siemens DCA Vantage
Siemens Dimension ExL
Siemens Dimension RxL
Siemens Dimension Vista
Siemens Dimension Xpand
Tosoh G7 Auto HPLC
Tosoh G8 Auto HPLC
Trinity Biotech HPLC
Trinity Biotech Premier
Ortho Vitros 5,1 FS, 4600, 5600

Table 2: Overall Variability for 2010-2015 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
(HbAS)	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