

College of American Pathologists (CAP) GH2 Survey Data:

(updated 12/14)

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 GH2 data for the **second** survey of 2014 are summarized below. The NGSP target or reference values are based on replicate analyses using seven NGSP certified secondary reference methods.

2014 GH2-B (fresh pooled samples)

		GH2-04			GH2-05			GH2-06		
^t NGSP %HbA1c Reference Value (95% CI)		6.58 (6.51-6.66)			8.39 (8.32-8.47)			5.65 (5.58-5.72)		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
* Abbott Architect c System	47	6.76	0.18	3.8	8.68	0.29	4.4	5.70	0.05	4.1
* Abbott Architect c System (enzymatic)	26	6.53	-0.05	1.6	8.39	0.00	1.7	5.53	-0.12	2.0
Abbott Architect i System	53	7.07	0.49	5.6	9.26	0.87	6.1	6.02	0.37	4.2
* Axis-Shield Afinion	64	6.55	-0.03	3.4	8.37	-0.02	3.0	5.73	0.08	2.5
* Beckman AU systems	67	6.45	-0.13	5.4	8.26	-0.13	5.7	5.50	-0.15	3.7
* Beckman UniCel DxC Synchron	172	6.57	-0.01	2.7	8.49	0.10	2.8	5.61	-0.04	2.6
* Bio-Rad D-10	217	6.60	0.02	2.8	8.45	0.06	2.2	5.69	0.04	2.7
* Bio-Rad Variant II	83	6.58	0.00	2.6	8.51	0.12	2.8	5.57	-0.08	2.7
* Bio-Rad Variant II Turbo	127	6.70	0.12	2.2	8.56	0.17	2.1	5.70	0.05	2.6
* Bio-Rad Variant II Turbo 2.0	124	6.64	0.06	2.6	8.54	0.15	2.3	5.65	0.00	3.1
* Roche Cobas c311	25	6.68	0.10	2.6	8.66	0.27	2.4	5.70	0.05	4.6
* Roche Cobas c500 series	350	6.63	0.05	2.8	8.39	0.00	2.8	5.73	0.08	2.9
* Roche Cobas Integra 400	60	6.63	0.05	4.3	8.55	0.16	4.2	5.65	0.00	4.1
* Roche Cobas Integra 800	135	6.68	0.10	2.8	8.63	0.24	2.3	5.76	0.11	2.6
* Sebia Capillarys 2 Flex Piercing	15	6.43	-0.15	2.0	8.32	-0.07	1.3	5.43	-0.22	1.1
* Siemens Advia Chemistry Systems	32	6.52	-0.06	4.3	8.33	-0.06	4.2	5.50	-0.15	6.0
* Siemens DCA 2000/2000+	29	6.51	-0.07	3.2	8.21	-0.18	3.3	5.52	-0.13	3.4
* Siemens DCA Vantage	307	6.44	-0.14	2.8	8.14	-0.25	3.0	5.45	-0.20	3.2
* Siemens Dimension ExL	185	6.76	0.18	2.6	8.35	-0.04	2.9	5.78	0.13	3.5
* Siemens Dimension RxL	67	6.77	0.19	3.0	8.34	-0.05	2.5	5.80	0.15	3.1
* Siemens Dimension Vista	269	6.81	0.23	3.1	8.40	0.01	2.5	5.73	0.08	2.9
* Siemens Dimension Xpand	59	6.76	0.18	3.0	8.32	-0.07	3.1	5.81	0.16	3.4
* Tosoh G7 Auto HPLC	88	6.77	0.19	1.9	8.70	0.31	1.8	5.81	0.16	2.0
* Tosoh G8 Auto HPLC	330	6.73	0.15	1.8	8.68	0.29	1.6	5.78	0.13	1.8
* Trinity Biotech HPLC	16	6.49	-0.09	1.8	8.38	-0.01	3.7	5.58	-0.07	2.6
* Trinity Biotech Premier Hb9210	50	6.56	-0.02	2.7	8.40	0.01	2.7	5.69	0.04	2.6
* (Ortho Clin Diag) Vitros 5,1 FS, 4600, 5600 Chem System	209	6.41	-0.17	2.2	8.32	-0.07	2.3	5.51	-0.14	2.4

* = NGSP certified at the time of the survey

^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.

Commentary by R. Little, Ph.D., NGSP Network Coordinator for the NGSP Steering Committee

In 2014, based on data from the GH2-B survey:

- Bias from the NGSP target and variability ($\pm 2SD$) are shown in the table above and in figure 1 for each method. The shaded rectangle (fig 1) reflects the current CAP acceptance limit of ± 6 . The method-specific biases were > 0.30 for all HbA1c levels for the Abbott Architect I System and > 0.30 for one level for the Tosoh G7 HPLC method.

- **Method-specific, between-laboratory CV's ranged from 1.1% to 6.1%. Three methods had CVs over 5% for at least one sample and 3 additional methods had at least one CV >4%; all of these methods were based on immunoassay. The lowest CVs ($\leq 2\%$) were seen for the Tosoh G7 and G8, the Sebia CE and the new Abbott Architect c System enzymatic method. Over 50% of laboratories are using methods with CVs <3% at all three HbA1c levels; over 90% of laboratories are using methods with CVs $\leq 3.5\%$ at all three HbA1c levels.**
- **The current pass limit for the GH2 survey is $\pm 6\%$. The overall pass rates for this survey were 93.5, 94.3 and 93.5 % of labs passing for the low, mid and high samples, respectively. For individual methods, the lowest pass rate was 29% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-B 2014). 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 nine surveys are shown in Table 1. Unfortunately, this 2014B survey's CVs were still above 3.5% at two levels; our goal is at or below 3.5% (Clin Chem 57:793-8, 2011). There continues to be a few methods with either high CVs or high bias (see table above). But there are also many methods that show consistent good performance.**

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.

Figure 1: Bias and Variability from the NGSP Target

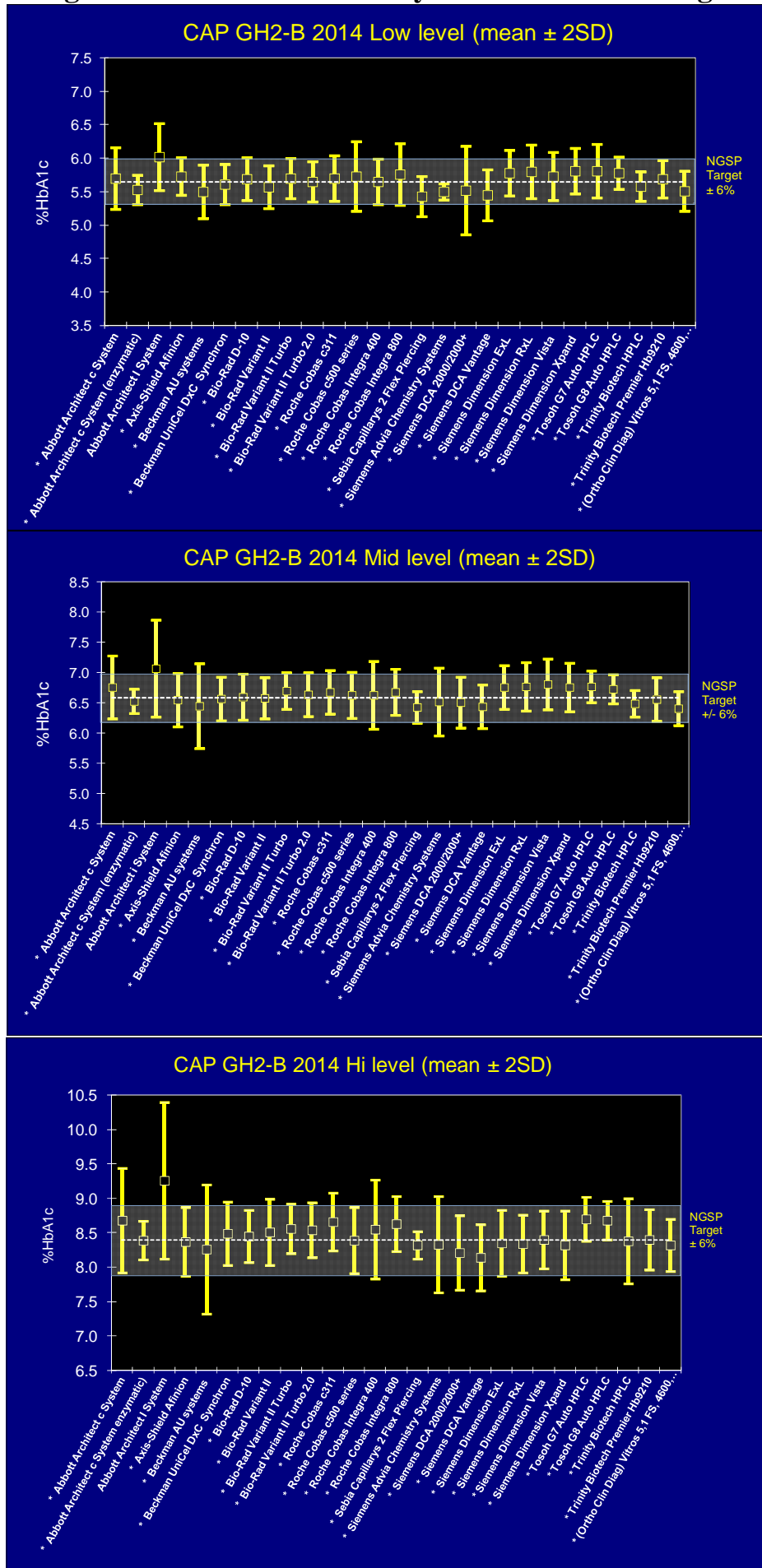


Table 1: Overall Variability for 2010-2014 for all GH2 participants

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