

# College of American Pathologists (CAP) GH2 Survey Data:

(updated 5/14)

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 **first** 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-A (fresh pooled samples)

		GH2-01			GH2-02			GH2-03		
<sup>t</sup> NGSP %HbA1c Reference Value (95% CI)		6.49 (6.44-6.53)			6.97 (6.92-7.02)			9.65 (9.60-9.70)		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
* Abbott Architect c System	58	6.69	0.20	4.7	7.20	0.23	3.7	9.96	0.31	3.9
Abbott Architect I System	53	6.44	-0.05	4.7	6.98	0.01	4.9	9.39	-0.26	5.6
* Axis-Shield Afinion	58	6.47	-0.02	3.7	6.85	-0.12	3.2	9.42	-0.23	3.2
* Beckman AU systems	55	6.28	-0.21	3.8	6.82	-0.15	4.4	9.45	-0.2	4.7
* Beckman UniCel DxC Synchron	191	6.50	0.01	3.0	6.95	-0.02	2.6	9.66	0.01	2.8
* Bio-Rad D-10	209	6.58	0.09	2.3	7.13	0.16	2.1	9.77	0.12	2.4
* Bio-Rad Variant II	84	6.44	-0.05	2.3	6.98	0.01	2.1	9.8	0.15	2.6
* Bio-Rad Variant II Turbo	151	6.57	0.08	2.5	7.13	0.16	2.2	9.84	0.19	2.2
* Bio-Rad Variant II Turbo 2.0	103	6.45	-0.04	2.0	7.03	0.06	2.0	9.71	0.06	1.7
* Roche Cobas c311	29	6.60	0.11	3.1	7.11	0.14	2.4	9.94	0.29	2.8
* Roche Cobas c500 series	316	6.52	0.03	2.5	6.95	-0.02	2.6	9.51	-0.14	2.7
* Roche Cobas Integra 400	50	6.46	-0.03	2.9	6.95	-0.02	2.9	9.73	0.08	3
* Roche Cobas Integra 800	136	6.57	0.08	2.2	7.05	0.08	2.2	9.79	0.14	2.1
* Sebia Capillarys 2 Flex Piercing	12	6.38	-0.11	1.4	6.86	-0.11	1.0	9.55	-0.1	0.5
* Siemens Advia Chemistry Systems	40	6.78	0.29	3.8	7.27	0.30	3.1	9.72	0.07	3.7
* Siemens DCA 2000/2000+	30	6.60	0.11	3.0	7.08	0.11	2.7	9.68	0.03	3.5
* Siemens DCA Vantage	305	6.46	-0.03	2.6	6.95	-0.02	2.8	9.61	-0.04	3.2
* Siemens Dimension ExL	188	6.85	0.36	3.3	7.25	0.28	3.4	9.64	-0.01	2.4
* Siemens Dimension RxL	86	6.88	0.39	3.7	7.27	0.30	3.1	9.67	0.02	2.4
* Siemens Dimension Vista	270	6.84	0.35	3.3	7.40	0.43	2.9	9.83	0.18	3.6
* Siemens Dimension Xpand	65	6.82	0.33	3.1	7.23	0.26	3.1	9.69	0.04	1.8
* Tosoh G7 Auto HPLC	102	6.81	0.32	1.9	7.33	0.36	1.9	10.06	0.41	1.9
* Tosoh G8 Auto HPLC	327	6.77	0.28	1.8	7.32	0.35	1.9	10.05	0.4	1.8
* Trinity Biotech HPLC	20	6.39	-0.10	1.9	6.77	-0.20	2.2	9.51	-0.14	3.1
* Trinity Biotech Premier Hb9210	41	6.42	-0.07	2.5	6.83	-0.14	2.4	9.51	-0.14	2.7
* (Ortho Clin Diag) Vitros 5,1 FS, 4600, 5600 Chem System	208	6.37	-0.12	2.7	6.85	-0.12	2.6	9.54	-0.11	2.8

\* = NGSP certified at the time of the survey

<sup>t</sup> Assigned as the mean of 3 replicate analyses per day for two days per method using 7 NGSP certified secondary reference methods. Gray shading indicates bias > 0.3% HbA1c or CV > 4%

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

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

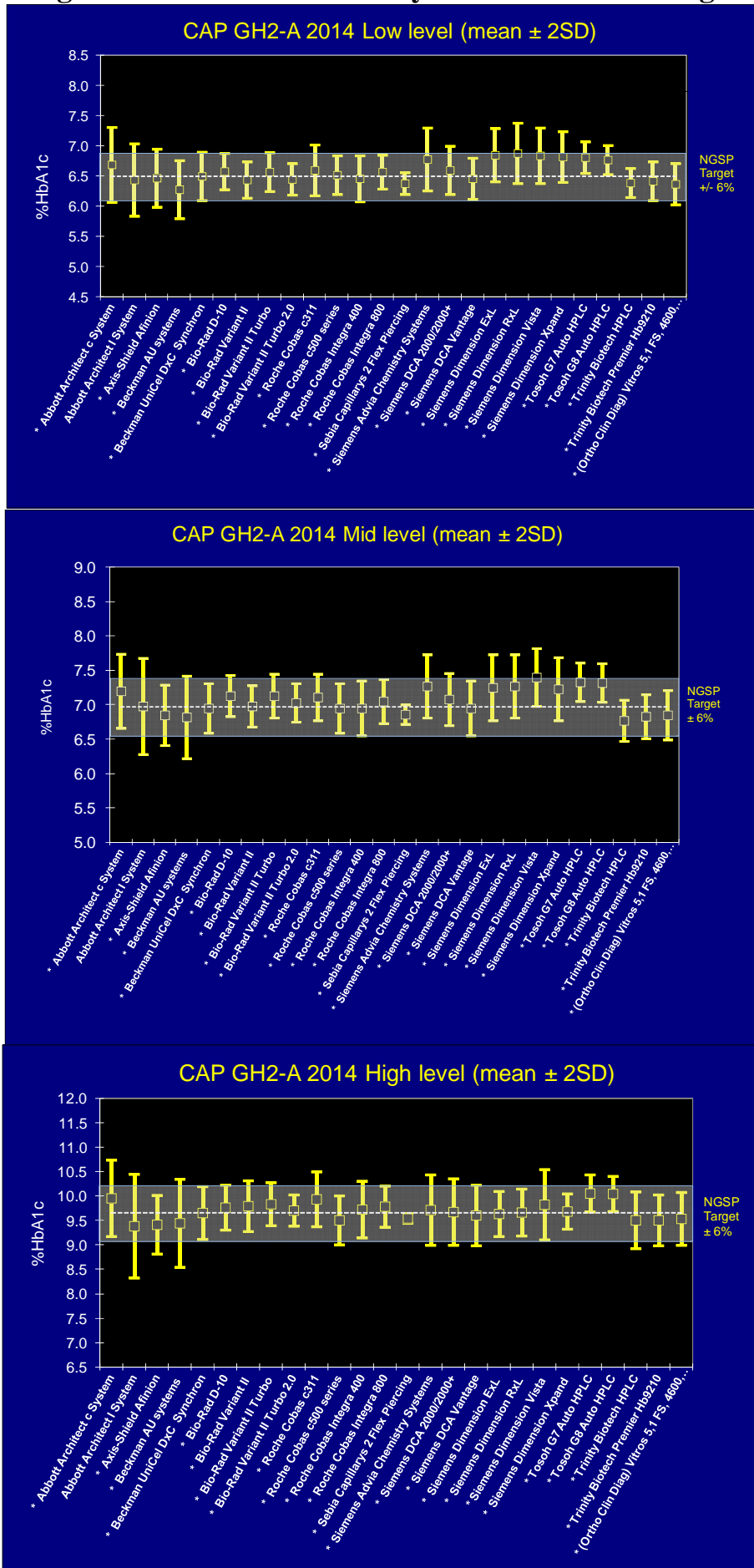
- Bias from the NGSP target and variability ( $\pm 2SD$ ) are shown in the table above and in figure 1 for each method. The shaded rectangle (fig 1) reflects the current CAP acceptance limit of  $\pm 6$ . The method-specific biases were over 0.30 for at least one level for all of the Siemens Dimension methods and both Tosoh HPLC methods.
- Method-specific, between-laboratory CV's ranged from 0.5% to 5.6%. Only one method had one CV over 5%; all other CVs were <5%. In general, the immunoassay methods had higher CVs than the HPLC or CE methods. The lowest CVs were seen for the Tosoh G7 and G8 and the Sebia CE

**method. Over 50% of laboratories are using methods with CVs <3% at all three HbA1c levels; about 85% 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 88.8, 89.1 and 94.2% of labs passing for the low, mid and high samples, respectively. For individual methods, the lowest pass rate was 57% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-A 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 2014A 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**

<b>Mailing</b>	<b>Sample#</b>	<b># of labs</b>	<b>Target</b>	<b>All method mean</b>	<b>S.D.</b>	<b>C.V.</b>
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