

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

(updated 5/12)

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 2012 are summarized below. The NGSP target or reference values are based on replicate analyses using seven NGSP certified secondary reference methods.

## 2012 GH2-A (fresh pooled samples)

		GH2-01			GH2-02			GH2-03		
NGSP Reference Value (%HbA1c) <sup>t</sup>		5.6			9.4			7.2		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
* Abbott Architect c	74	5.46	-0.14	3.6	9.36	-0.04	4.3	7.10	-0.10	3.1
* Axis-Shield Afinion	28	5.59	-0.01	3.1	8.98	-0.42	2.9	7.17	-0.03	2.5
* Bayer (Metrika) A1cNOW <sup>#</sup>	28	5.14	-0.46	3.8	8.49	-0.91	6.3	6.59	-0.61	5.4
* Beckman AU systems	35	5.59	-0.01	4.2	9.31	-0.09	3.6	7.20	0.00	3.4
* Beckman Synchron LX Systems	21	5.77	0.17	4.7	9.45	0.05	2.9	7.15	-0.05	2.8
* Beckman UniCel DxC Synchron	300	5.61	0.01	3.8	9.53	0.13	3.9	7.11	-0.09	3.5
* Bio-Rad D-10	244	5.68	0.08	2.7	9.64	0.24	2.6	7.55	0.35	2.7
* Bio-Rad in2it	10	5.41	-0.19	7.0	9.01	-0.39	3.0	7.24	0.04	5.4
* Bio-Rad Variant II	111	5.60	0.00	2.8	9.61	0.21	2.5	7.46	0.26	2.5
* Bio-Rad Variant II Turbo	183	5.53	-0.07	2.6	9.52	0.12	2.2	7.35	0.15	2.1
* Bio-Rad Variant II Turbo 2.0	47	5.69	0.09	3.0	9.64	0.24	1.7	7.54	0.34	2.5
* Roche Cobas c311	12	5.55	-0.05	5.0	9.53	0.13	5.7	7.23	0.03	4.1
* Roche Cobas c500/700	248	5.62	0.02	2.5	9.26	-0.14	2.6	7.15	-0.05	2.4
* Roche Cobas Integra 400	53	5.60	0.00	2.8	9.50	0.10	2.8	7.33	0.13	2.4
* Roche Cobas Integra 800	144	5.65	0.05	2.1	9.51	0.11	2.3	7.24	0.04	2.2
* Roche/Hitachi Modular P	14	5.61	0.01	2.9	9.29	-0.11	3.8	7.21	0.01	2.4
* Siemens Advia New Reagent	41	5.35	-0.25	5.1	9.01	-0.39	6.7	7.02	-0.18	5.7
* Siemens Advia Original Reagent	20	5.80	0.20	3.3	9.69	0.29	5.1	7.53	0.33	4.2
* Siemens DCA 2000/2000+	71	5.61	0.01	2.7	9.25	-0.15	3.2	7.19	-0.01	3.3
* Siemens DCA Vantage	253	5.56	-0.04	2.7	9.18	-0.22	3.1	7.14	-0.06	2.7
* Siemens Dimension ExL new reagent	62	5.77	0.17	3.3	9.57	0.17	3.3	7.34	0.14	2.7
* Siemens Dimension ExL orig reagent	29	5.75	0.15	2.6	9.22	-0.18	3.0	7.08	-0.12	4.2
* Siemens Dimension RxL new reagent	114	5.67	0.07	3.0	9.62	0.22	2.7	7.29	0.09	2.8
* Siemens Dimension RxL orig reagent	76	5.72	0.12	3.0	9.22	-0.18	3.1	7.07	-0.13	2.5
* Siemens Dimension Vista new reagent	181	5.63	0.03	4.5	9.11	-0.29	4.0	7.33	0.13	4.0
* Siemens Dimension Xpand new reagent	65	5.63	0.03	3.8	9.58	0.18	3.5	7.27	0.07	3.3
* Siemens Dimension Xpand orig reagent	37	5.66	0.06	2.6	9.19	-0.21	3.4	7.06	-0.14	2.8
* Tosoh G7 Auto HPLC	184	5.73	0.13	2.1	9.76	0.36	1.7	7.58	0.38	1.6
* Tosoh G8 Auto HPLC	260	5.71	0.11	1.5	9.75	0.35	1.2	7.58	0.38	1.3
* Trinity Biotech HPLC (Affinity)	31	5.76	0.16	3.1	9.25	-0.15	2.5	7.31	0.11	2.3
* (Ortho Clin Diag) Vitros 5,1 FS Chem System	210	5.42	-0.18	2.3	9.34	-0.06	2.6	7.01	-0.19	2.4

\* = 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.

<sup>#</sup> EDTA in the CAP sample has been shown by the manufacturer of A1cNow+ to cause artificially low results by this method. Routine samples for this method are from fingerstick and do not include EDTA. The manufacturer recommends the use of heparin anticoagulant instead of EDTA when testing venous samples

Gray shading indicates bias > 0.3% HbA1c or CV > 5% (except Bayer A1cNow bias)

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

In 2012, based on data from the GH2-A survey:

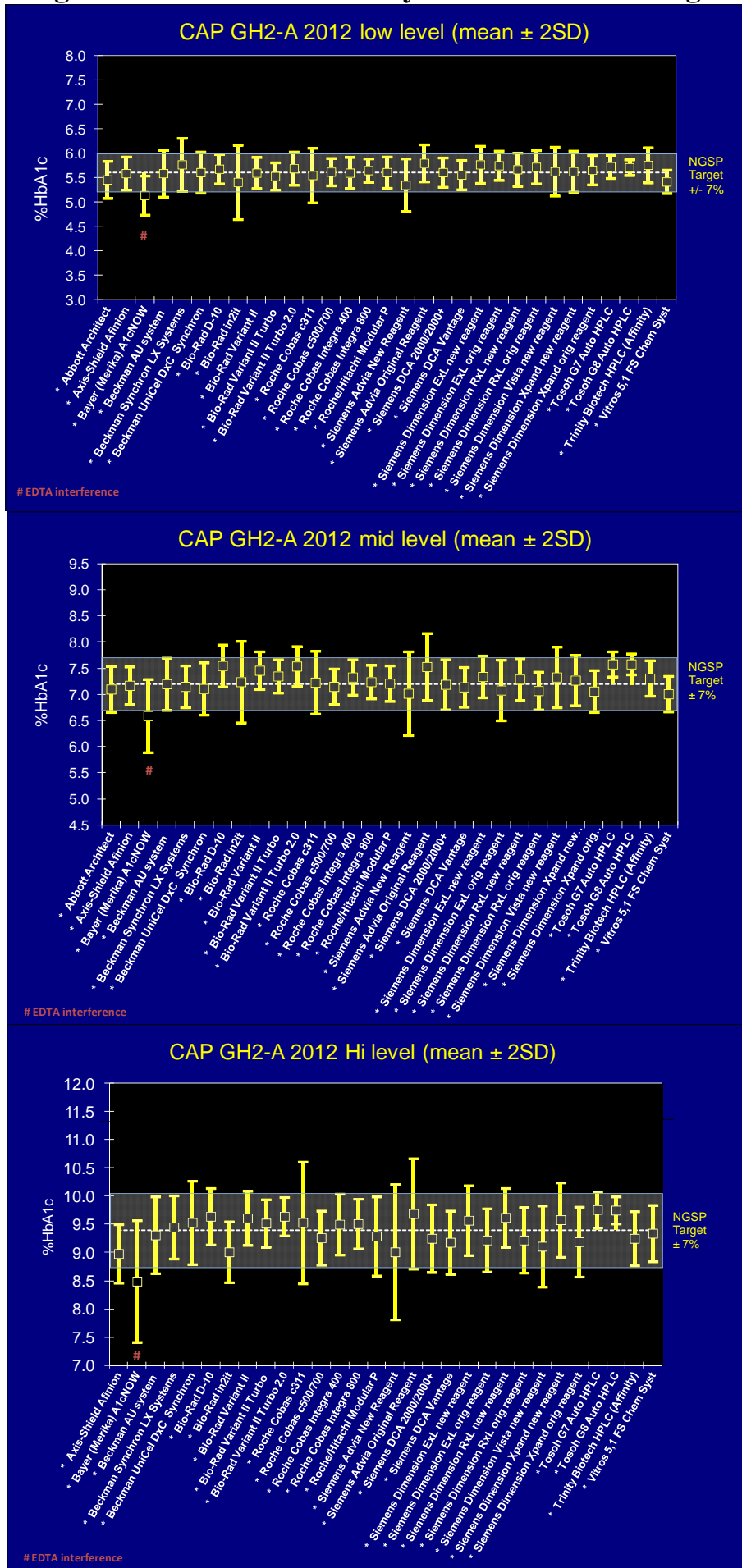
- Bias from the NGSP target and variability ( $\pm 2SD$ ) are shown in the table above and in figure 1 for each method. The shaded rectangle (fig 1) reflects the current CAP acceptance limit of  $\pm 7\%$ . In addition to the Bayer A1cNow<sup>#</sup> (see footnote above), the method-specific biases were over 0.30 for 8

methods for one or more levels: Axis-Shield Afinion, Bio-Rad D-10, Bio-Rad in2it, Bio-Rad VII Turbo 2.0, Siemens Advia original and new reagent, and Tosoh G7 and G8.

- **Method-specific, between-laboratory CV's ranged from 1.2% to 7.0%. All but 4 methods (in2it, Advia new and original, Cobas c311) had CVs below 5% for all three levels. Approximately 97% of laboratories were using methods that had between-lab CVs <5.0% at all three HbA1c levels; only about 20% of laboratories are using methods with CVs <3% at all three HbA1c levels.**
- **The current pass limit for the GH2 survey is  $\pm 7\%$ . The overall pass rate for this survey was 95.6, 96.2 and 94.9% of labs passing for the low, mid and high samples, respectively. For individual methods, the lowest pass rate was 72.7% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-A 2012). 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 five surveys are shown in Table 1. This 2012A 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 or both. 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 2010-2012 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