

College of American Pathologists (CAP) GH2 Survey Data:

(updated 12/11)

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 2011 are summarized below. The NGSP target or reference values are based on replicate analyses using seven NGSP certified secondary reference methods.

2011 GH2-B (fresh pooled samples)

		GH2-04			GH2-05			GH2-06		
NGSP Reference Value (%HbA1c) ^t		6.3			7.6			9.2		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
* Abbott Architect c	66	6.14	-0.16	3.9	7.45	-0.15	4.0	8.97	-0.23	5.3
* Axis-Shield Afinion	19	6.34	0.04	3.0	7.58	-0.02	2.6	9.21	0.01	4.0
* Bayer (Metrika) A1cNOW [#]	24	5.81	-0.49	4.4	6.94	-0.66	4.9	8.22	-0.98	6.2
* Beckman AU systems	25	6.30	0.00	5.0	7.64	0.04	4.5	9.22	0.02	5.5
* Beckman Synchron LX Systems	29	6.20	-0.10	4.6	7.69	0.09	3.7	9.54	0.34	4.5
* Beckman UniCel Dx C Synchron	270	6.22	-0.08	3.3	7.55	-0.05	3.2	9.37	0.17	3.4
* Bio-Rad D-10	215	6.55	0.25	2.8	7.92	0.32	2.3	9.46	0.26	2.7
* Bio-Rad in2it	11	6.18	-0.12	3.8	7.55	-0.05	2.6	9.11	-0.09	4.0
* Bio-Rad Variant II	96	6.45	0.15	3.0	7.82	0.22	2.7	9.45	0.25	2.3
* Bio-Rad Variant II Turbo	166	6.43	0.13	2.4	7.82	0.22	2.5	9.36	0.16	2.8
* Bio-Rad Variant II Turbo 2.0	33	6.58	0.28	2.9	7.95	0.35	2.9	9.41	0.21	2.4
* Roche Cobas c311	12	6.29	-0.01	3.4	7.68	0.08	2.2	9.35	0.15	4.1
* Roche Cobas c500/700	210	6.23	-0.07	2.9	7.50	-0.10	2.5	9.07	-0.13	2.8
* Roche Cobas Integra 400	47	6.33	0.03	2.6	7.71	0.11	2.8	9.34	0.14	2.7
* Roche Cobas Integra 800	127	6.31	0.01	1.8	7.68	0.08	2.1	9.37	0.17	2.2
* Roche/Hitachi Modular P	10	6.32	0.02	4.6	7.49	-0.11	4.0	9.13	-0.07	5.4
* Siemens Advia New Reagent	38	6.29	-0.01	3.8	7.54	-0.06	4.0	9.00	-0.20	4.7
* Siemens Advia Original Reagent	19	6.58	0.28	1.8	7.95	0.35	2.6	9.52	0.32	2.4
* Siemens DCA 2000/2000+	59	6.26	-0.04	3.1	7.66	0.06	3.5	9.17	-0.03	2.9
* Siemens DCA Vantage	196	6.25	-0.05	2.5	7.53	-0.07	3.1	9.02	-0.18	3.2
* Siemens Dimension ExL new reagent	32	6.39	0.09	3.9	7.67	0.07	2.4	9.26	0.06	3.2
* Siemens Dimension ExL original reagent	34	6.32	0.02	4.2	7.52	-0.08	3.5	9.20	0.00	2.8
* Siemens Dimension RxL new reagent	76	6.42	0.12	2.5	7.66	0.06	2.0	9.26	0.06	2.4
* Siemens Dimension RxL original reagent	102	6.33	0.03	3.2	7.48	-0.12	2.8	9.09	-0.11	3.0
* Siemens Dimension Vista new reagent	121	6.59	0.29	2.8	7.80	0.2	2.9	9.00	-0.20	2.0
* Siemens Dimension Vista original reagent	25	6.48	0.18	3.9	8.03	0.43	2.0	9.15	-0.05	1.3
* Siemens Dimension Xpand new reagent	33	6.39	0.09	3.4	7.56	-0.04	3.0	9.24	0.04	2.1
* Siemens Dimension Xpand original reagent	47	6.30	0.00	2.7	7.46	-0.14	2.7	9.15	-0.05	2.7
* Tosoh G7 Auto HPLC	181	6.62	0.32	2.2	8.01	0.41	2.0	9.56	0.36	2.0
* Tosoh G8 Auto HPLC	212	6.58	0.28	1.5	7.99	0.39	1.4	9.54	0.34	1.4
* Trinity Biotech HPLC (Affinity)	20	6.41	0.11	3.8	7.68	0.08	2.3	9.29	0.09	2.1
* (Ortho Clin Diag) Vitros 5,1 FS Chem System	183	6.14	-0.16	2.3	7.59	-0.01	2.5	9.42	0.22	3

* = 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 7 NGSP certified secondary reference methods.

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 2011, 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 $\pm 7\%$. In addition to the Bayer A1cNow[#] (see footnote above), the method-specific biases were over 0.30 for 5 methods for one or more levels: Beckman Synchron LX, Bio-Rad Turbo 2.0, Siemens Advia original reagent, and Tosoh G7 and G8. For one of these methods, the bias was high at all 3 HbA1c levels and higher than 0.40 at one level (Tosoh G7). This is quite disappointing given the much better performance in the last survey (2011A).**
- **Method-specific, between-laboratory CV's ranged from 1.4% to 5.5%. All but 3 methods (Abbott Architect, Beckman AU, and Roch Hitachi Modular P) had CVs below 5% for all three levels. Approximately 96% of laboratories were using methods that had between-lab CVs <5.0% at all three HbA1c levels, and approximately 50% 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 96.1, 96.1, and 95.2% of labs passing for the low, mid and high samples, respectively. For individual methods, the lowest pass rate was 81.3% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-B 2011). 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 four surveys are shown in Table 1. The overall CVs for all methods in all laboratories have decreased over the last few years but this 2011B survey's CVs were slightly higher than for the last survey of this year; 3.7 – 3.8% compared to 3.2 - 3.5%. 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. One significant change from previous surveys is the very high bias of both Tosoh HPLC methods 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.

Figure 1: Bias and Variability from the NGSP Target

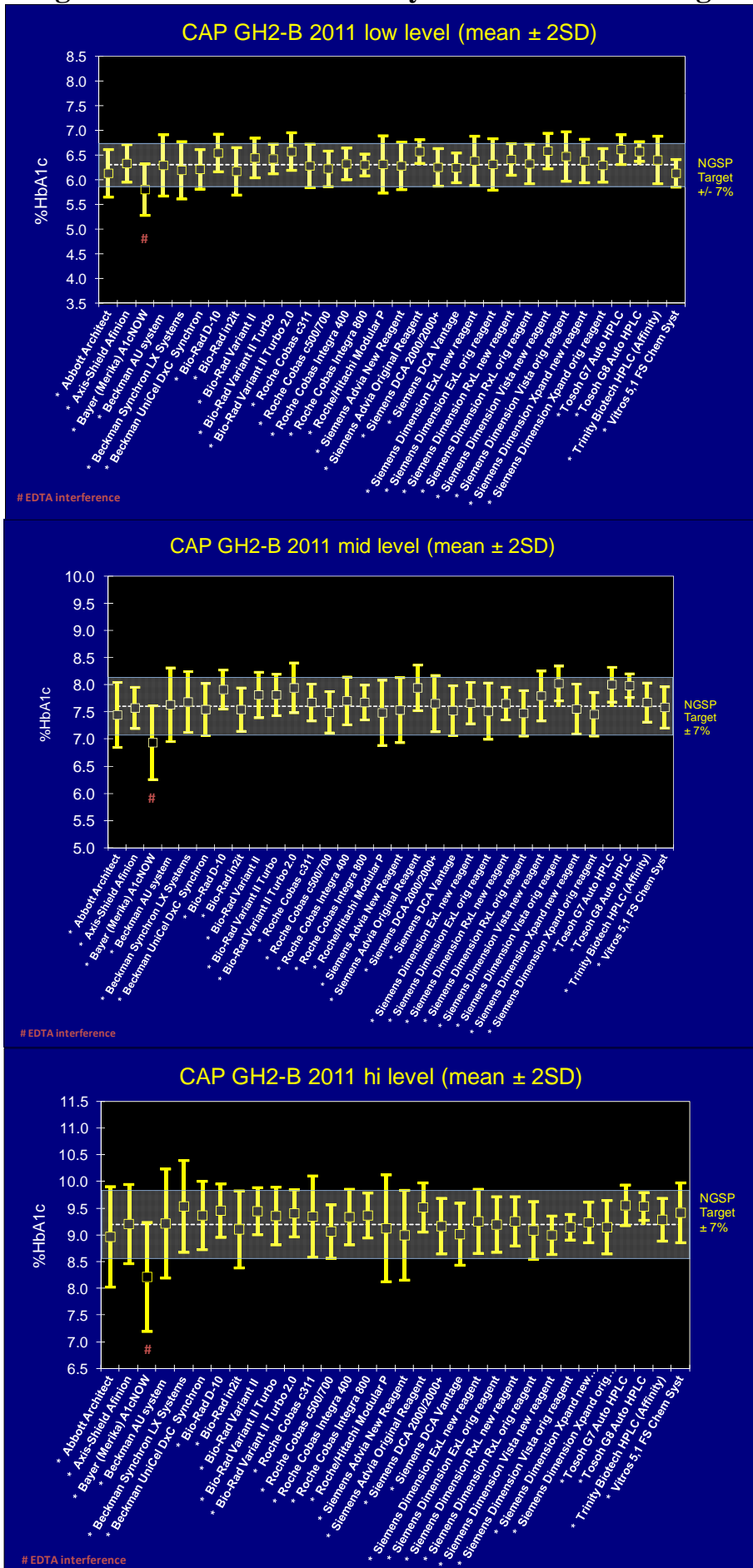


Table 1: Overall Variability for 2010-2011 for all GH2 participants

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