

College of American Pathologists (CAP) GH2 Survey Data:

(updated 12/12)

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 **second** 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-B (fresh pooled samples)

		GH2-04			GH2-05			GH2-06 (HbAS)		
NGSP Reference Value (%HbA1c) ^t		5.40			8.30			5.65		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
* Abbott Architect c	83	5.40	0.00	4.4	8.28	-0.02	3.8	6.80	1.15	3.4
* Axis-Shield Afinion	23	5.54	0.14	4.1	8.10	-0.20	3.4	5.65	0.00	3.5
* Bayer (Merika) A1cNOW [#]	23	5.05	-0.35	4.0	7.49	-0.81	6.2	6.31	0.66	4.9
* Beckman AU system	37	5.34	-0.06	3.3	8.15	-0.15	3.9	6.66	1.01	3.6
* Beckman Synchron LX Systems	17	5.49	0.09	4.0	8.22	-0.08	3.2	5.62	-0.03	6.5
* Beckman UniCel DxC Synchron	268	5.39	-0.01	3.3	8.24	-0.06	3.3	5.48	-0.17	3.1
* Bio-Rad D-10	230	5.55	0.15	2.9	8.50	0.20	2.5	5.80	0.15	3.0
* Bio-Rad in2it	11	5.30	-0.10	5.2	8.13	-0.17	3.9	5.55	-0.10	7.1
* Bio-Rad Variant II	103	5.32	-0.08	2.7	8.36	0.06	2.3	5.68	0.03	3.7
* Bio-Rad Variant II Turbo	174	5.40	0.00	2.9	8.42	0.12	2.5	5.66	0.01	4.2
* Bio-Rad Variant II Turbo 2.0	48	5.50	0.10	2.1	8.52	0.22	1.9	5.96	0.31	3.8
* Roche Cobas c311	15	5.50	0.10	5.0	8.33	0.03	5.8	5.70	0.05	12.2
* Roche Cobas c500/700	262	5.50	0.10	2.5	8.12	-0.18	2.5	5.61	-0.04	2.6
* Roche Cobas Integra 400	51	5.47	0.07	3.2	8.40	0.10	3.8	5.65	0.00	3.3
* Roche Cobas Integra 800	145	5.51	0.11	2.5	8.26	-0.04	2.0	5.65	0.00	2.4
* Siemens Advia A1c 3 Reagent	59	5.56	0.16	5.7	8.54	0.24	5.6	5.90	0.25	6.9
* Siemens DCA 2000/2000+	58	5.46	0.06	2.8	8.28	-0.02	3.0	5.77	0.12	3.1
* Siemens DCA Vantage	261	5.44	0.04	2.6	8.17	-0.13	2.6	5.78	0.13	2.8
* Siemens Dimension ExL new reagent	113	5.67	0.27	3.3	8.08	-0.22	3.1	5.90	0.25	3.7
* Siemens Dimension RxL new reagent	131	5.70	0.30	3.4	8.18	-0.12	3.6	5.92	0.27	3.0
* Siemens Dimension RxL orig reagent	11	5.55	0.15	2.8	8.09	-0.21	2.6	5.82	0.17	2.5
* Siemens Dimension Vista new reagent	192	5.72	0.32	4.0	8.61	0.31	2.8	5.95	0.30	3.4
* Siemens Dimension Xpand new reagent	69	5.66	0.26	3.3	8.10	-0.20	2.8	5.90	0.25	3.5
* Siemens Dimension Xpand orig reagent	13	5.65	0.25	2.6	8.13	-0.17	2.1	5.76	0.11	2.6
* Tosoh G7 Auto HPLC	145	5.65	0.25	2.1	8.61	0.31	1.8	5.65	0.00	2.1
* Tosoh G8 Auto HPLC	284	5.62	0.22	1.5	8.58	0.28	1.3	5.64	-0.01	1.8
* Trinity Biotech HPLC (Affinity)	30	5.53	0.13	1.8	8.28	-0.02	2.3	5.69	0.04	1.8
* Vitros 5,1 FS Chem Syst	212	5.28	-0.12	2.0	8.10	-0.20	2.4	5.41	-0.24	2.6

* = NGSP certified at the time of the survey

^t For GH2-04 and 05 values were assigned as the mean of 3 replicate analyses per day for two days per method using 7 NGSP certified secondary reference methods. For GH2-06, values were assigned by only two NGSP SRLs (boronate affinity HPLC only) due to presence of HbS trait.

[#] 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-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 $\pm 7\%$. For samples that did not contain a Hb variant (GH2-04 and GH2-05), in addition to the Bayer A1cNow[#] (see footnote above), only two methods showed biases over 0.30% HbA1c: Siemens Dimension Vista

(both levels) and Tosoh G7 (high level). Sample GH2-06 included HbS (HbAS, sickle cell trait). Three methods showed a clear positive bias due to HbS (Abbott Architect c, Bayer A1cNOW and Beckman AU system). One additional method (Bio-Rad Variant II Turbo 2.0) showed a slightly high bias compared to the GH2-04 normal HbA1c level sample (bias of 0.31% vs. 0.10% HbA1c, respectively), this warrants further investigation since the method is listed as not having interference from HbS on the NGSP website.

- Method-specific, between-laboratory CV's ranged from 1.3% to 6.2% for the two HbAA samples. All but 4 methods (Bio-Rad in2it, Siemens Advia A1c_3, Bayer A1c NOW and Roche 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; 62% of laboratories are using methods with CVs <3% at both HbA1c levels.
- The current pass limit for the GH2 survey is $\pm 7\%$. The overall pass rate for this survey was 93.1, 95.4 and 90.1% of labs passing for the low, high and low HbS samples, respectively. For individual methods, the lowest pass rate was 0% (for the HbS sample) and 71.9% for HbAA, and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-B 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 six surveys are shown in Table 1. This 2012B survey's CVs were still above 3.5% at both (HbAA) 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 many methods 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

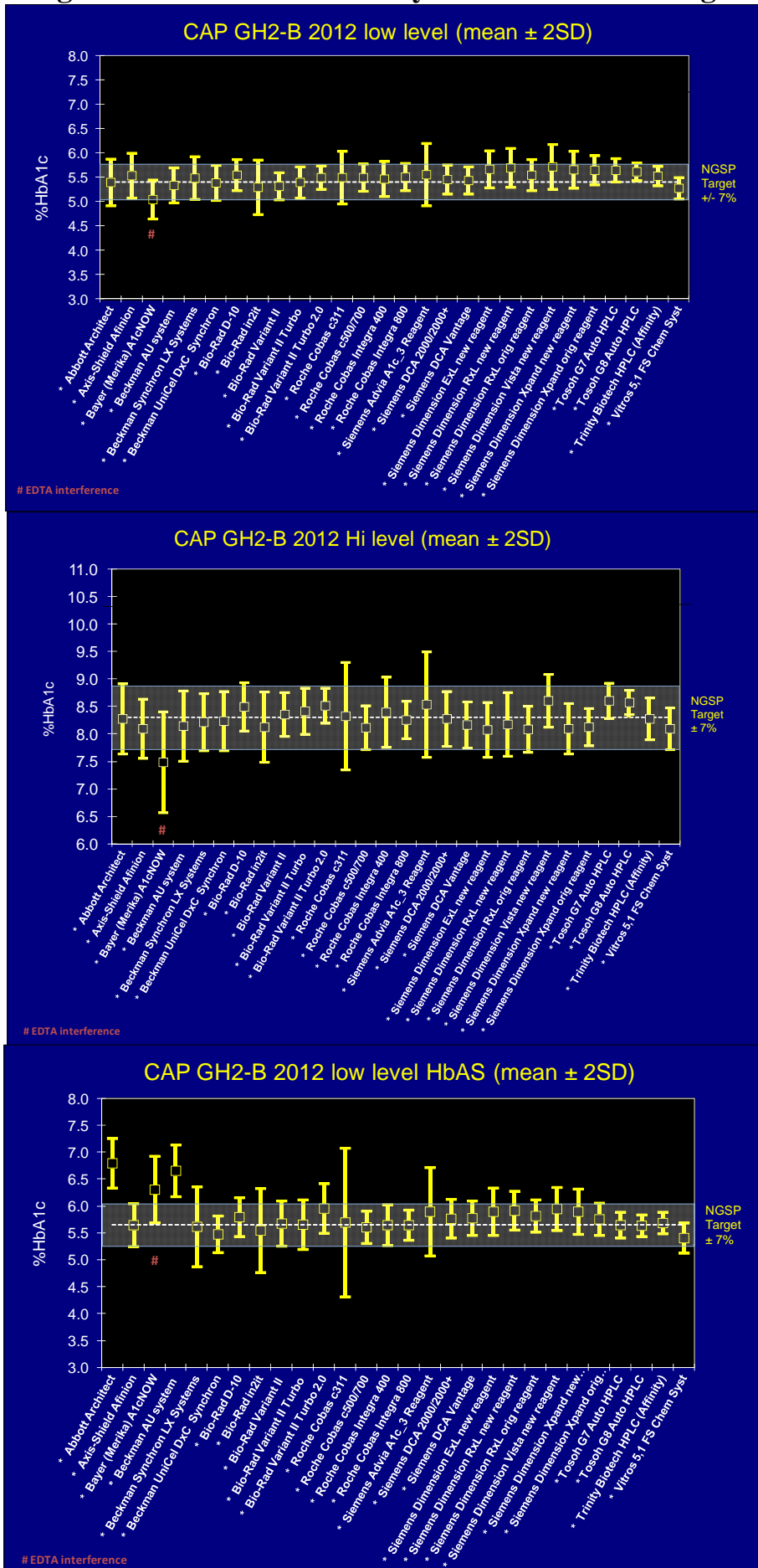


Table 1: Overall Variability for 2010-2012 for all GH2 participants

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