

College of American Pathologists (CAP) GH2 Survey Data:

(updated 5/10)

The American Diabetes Association (ADA) recommends that laboratories use only HbA1c assay methods that have been NGSP certified and report results as “%HbA1c” or “%HbA1c equivalents”. 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 2010 are summarized below. The NGSP target or reference values are based on replicate analyses using seven NGSP certified secondary reference methods.

2010 GH2-A (fresh pooled samples)

		GH2-01			GH2-02			GH2-03		
NGSP Reference Value (%HbA1c) ^t		5.90			9.80			7.40		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
* Abbott Architect	52	5.94	0.04	5.0	9.98	0.18	3.9	7.56	0.16	5.2
* Axis-Shield Afinion	16	6.19	0.29	3.6	9.87	0.07	3.3	7.49	0.09	3.5
* Metrika A1cNOW [#]	21	5.63	-0.27	5.6	9.09	-0.71	4.6	6.84	-0.56	3.5
* Beckman Synchron CX Systems	24	5.79	-0.11	5.2	9.51	-0.29	4.3	7.11	-0.29	6.0
* Beckman Synchron LX Systems	69	5.83	-0.07	4.4	9.71	-0.09	4.3	7.16	-0.24	3.6
* Beckman UniCel DxC Synchron	241	5.82	-0.08	3.1	9.60	-0.20	3.3	7.11	-0.29	3.0
* Bio-Rad D-10	198	6.09	0.19	2.6	10.00	0.20	2.5	7.56	0.16	2.4
* Bio-Rad in2it	10	6.10	0.20	3.6	10.28	0.48	5.6	7.41	0.01	5.7
* Bio-Rad Variant II	118	6.14	0.24	3.1	10.07	0.27	2.3	7.64	0.24	2.7
* Bio-Rad Variant II Turbo	143	6.04	0.14	3.0	9.66	-0.14	2.3	7.50	0.10	2.3
* Bio-Rad Variant II Turbo 2.0	19	6.27	0.37	2.0	9.93	0.13	2.0	7.67	0.27	1.7
* Olympus AU system	19	5.74	-0.16	3.9	9.67	-0.13	5.1	7.39	-0.01	4.5
* Roche Cobas c501	133	6.07	0.17	2.8	9.51	-0.29	3.0	7.40	0.0	2.8
* Roche Cobas Integra 400	42	6.10	0.20	2.5	9.89	0.09	2.5	7.68	0.28	2.8
* Roche Cobas Integra 800	115	6.07	0.17	3.0	9.80	0.00	2.5	7.55	0.15	2.5
* Roche/Hitachi Modular P	14	5.95	0.05	2.9	9.63	-0.17	4.1	7.24	-0.16	2.1
* Siemens Advia	47	5.86	-0.04	5.7	9.73	-0.07	4.3	7.49	0.09	4.5
* Siemens Advia New Reagent	21	5.63	-0.27	4.0	9.61	-0.19	4.0	7.31	-0.09	4.1
* Siemens Advia Original Reagent	13	6.03	0.13	2.7	9.65	-0.15	4.1	7.51	0.11	3.5
* Siemens DCA 2000/2000+	84	6.07	0.17	2.8	9.66	-0.14	3.2	7.5	0.1	2.4
* Siemens DCA Vantage	118	6.07	0.17	2.2	9.62	-0.18	3.2	7.44	0.04	2.6
* Siemens Dimension ExL	39	6.03	0.13	2.2	9.60	-0.20	4.0	7.19	-0.21	2.4
* Siemens Dimension RxL	294	6.03	0.13	3.1	9.53	-0.27	4.2	7.21	-0.19	3.1
* Siemens Dimension Vista	61	5.65	-0.25	2.7	9.23	-0.57	1.7	7.64	0.24	3.8
* Siemens Dimension Xpand	126	5.95	0.05	3.3	9.44	-0.36	4.0	7.13	-0.27	3.1
* Tosoh A1c 2.2 Plus	46	6.21	0.31	2.8	9.96	0.16	2.9	7.66	0.26	2.8
* Tosoh G7 Auto HPLC	202	6.12	0.22	1.8	9.80	0.00	1.4	7.56	0.16	1.5
* Tosoh G8 Auto HPLC	116	6.10	0.20	1.9	9.80	0.00	1.5	7.56	0.16	1.5
* Trinity Biotech HPLC (Affinity)	18	5.85	-0.05	3.3	9.69	-0.11	1.6	7.36	-0.04	3.5
* Vitros 5,1 FS Chem System	132	6.27	0.37	3.4	10.20	0.40	3.7	7.85	0.45	3.7

* = 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 > 0.35% HbA1c or CV > 5%

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

In 2010, based on data from the GH2-A survey:

- **Only HbA1c results are included in this CAP survey report. Laboratories should not be reporting total GHB; these results are no longer included in the CAP summary report.**
- **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 reflects the current CAP acceptance limit of $\pm 8\%$. Other than the Bayer A1cNow[#] (see footnote above), the method-specific means were all within 0.4, 0.5 and 0.6% HbA1c of NGSP targets at the low, mid and high HbA1c levels, respectively (table above). This is somewhat higher than for the last few surveys. There were a few methods that showed unusually large biases for at least one sample (gray shading in table); the Ortho Clinical Vitros showed high bias ($>0.35\%$ HbA1c) for all three samples, the Siemens Dimension Vista showed a low bias (-0.57% HbA1c) for the high level sample, the Bio-Rad Variant II Turbo 2.0, a new method, showed a high bias (0.37% HbA1c) for the normal range sample, and the Bio-Rad in2it showed a high bias (0.48% HbA1c) on the high level sample. Many methods showed less than 0.3% HbA1c bias for all levels.**
- **Method-specific, between-laboratory CV's ranged from 1.4% to 6.0%. Six methods showed CVs $>5\%$ for at least 1 level (gray shading in table). However, approximately 93% of laboratories were using methods that had between-lab CVs $<5.0\%$ at all three HbA1c levels.**
- **This is the fifth GH2 survey using an accuracy based target (NGSP); peer group means are no longer used for grading the GH2 survey (except for the Bayer method due to its EDTA interference). The acceptable limit for this survey is $\pm 8\%$ of the target value; the acceptable limit for grading is projected to be $\pm 6\%$ in 2011. The overall pass rate for this survey ranged from 95.2 to 95.5%, depending upon the HbA1c level. For individual methods, the lowest pass rate was 79.0% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-A 2010). 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.**
- **Figure 2 examines the CV trends for the 2006 through 2010 surveys for the 11 most used methods. The survey samples are grouped by HbA1c level: Low Level: 4-6.0 % HbA1c, Medium Level: 6.1-8.0% HbA1c, and High Level: 8.1-10% HbA1c. There appears to be a decrease in the CVs over time for most methods, especially in the low HbA1c range.**

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

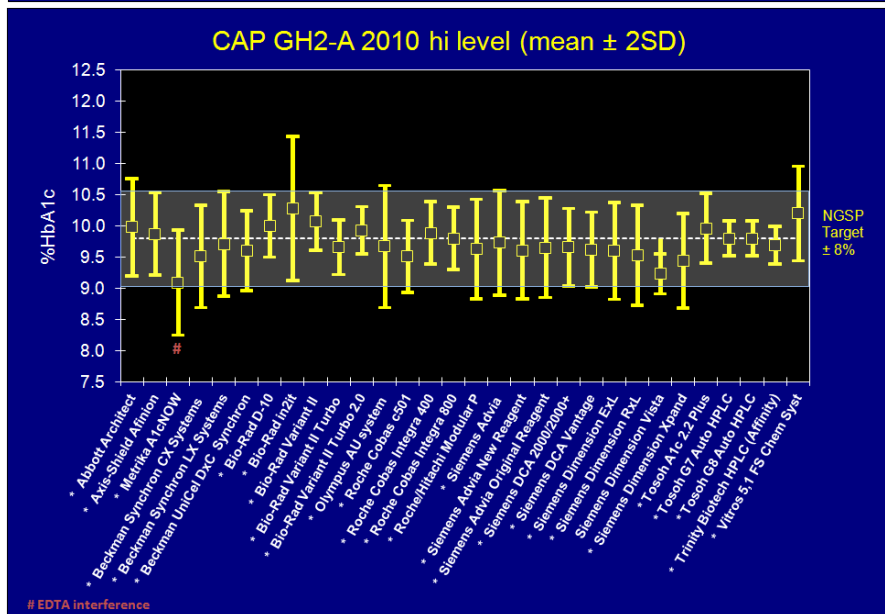
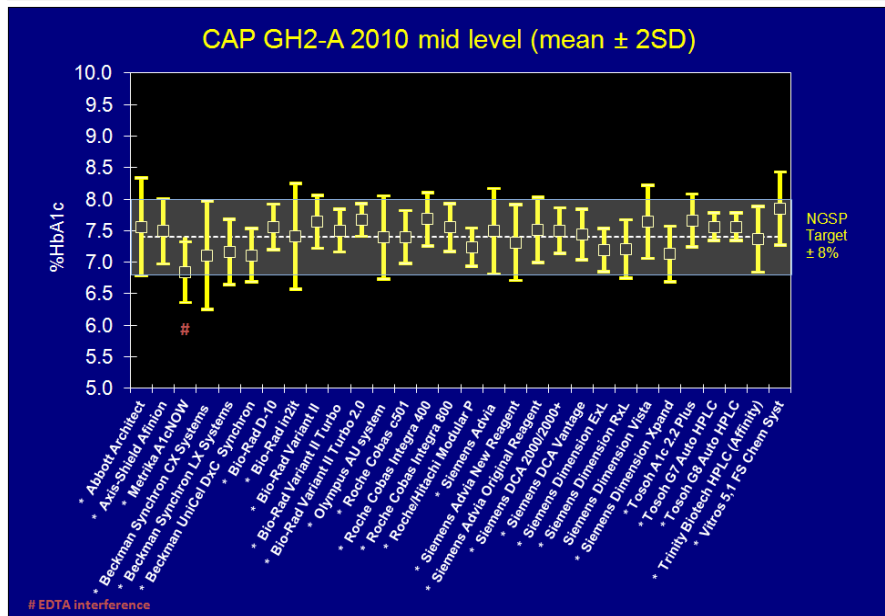
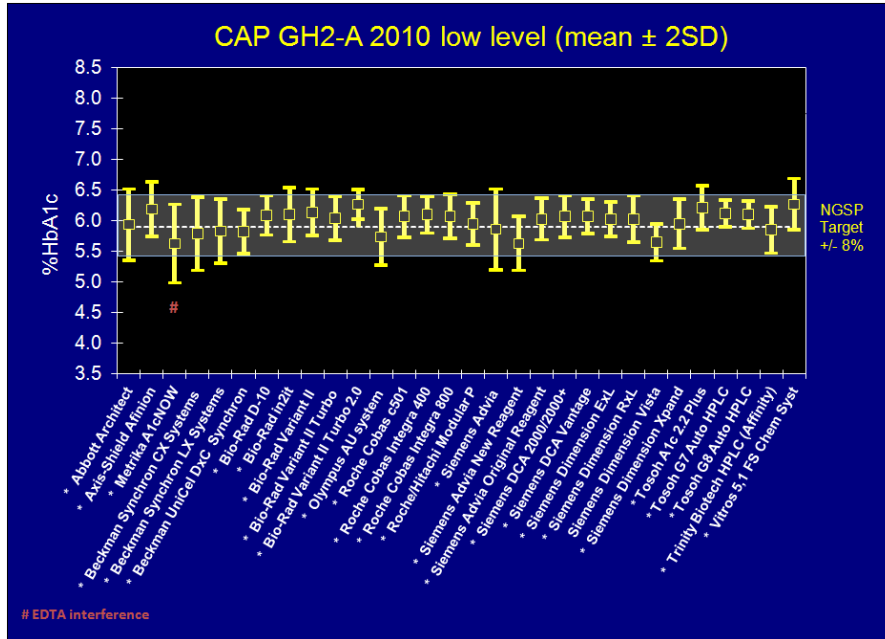


Figure 1: CV Trends for 2006 thru 2010 Surveys

