College of American Pathologists (CAP) GH2 Survey Data:

(updated 12/10)

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 2010 are summarized below. The NGSP target or reference values are based on replicate analyses using seven NGSP certified secondary reference methods.

2010 GH2-B (fresh pooled samples)

		GH2-04			GH2-05			GH2-06		
NGSP Reference Value (%HbA1c)[t]		**5.2**			**8.7**			**6.3**		
	no. labs	**Mean %HbA1c**	**Mean bias**	**% CV**	**Mean %HbA1c**	**Mean bias**	**% CV**	**Mean %HbA1c**	**Mean bias**	**% CV**
* **Abbott Architect**	53	5.02	-0.18	5.9	8.74	0.04	3.5	6.22	-0.08	4.2
* **Axis-Shield Afinion**	11	5.57	0.37	2.8	8.75	0.05	1.9	6.61	0.31	1.8
* **Bayer (Metrika) A1cNOW[#]**	25	4.86	-0.34	4.7	8.02	-0.68	6.0	5.85	-0.45	4.9
* **Beckman AU system**	17	5.26	0.06	5.3	8.65	-0.05	5.0	6.21	-0.09	4.8
* **Beckman Synchron CX Systems**	16	5.25	0.05	4.0	8.15	-0.55	4.1	6.12	-0.18	3.6
* **Beckman Synchron LX Systems**	59	5.42	0.22	5.2	8.61	-0.09	5.3	6.32	0.02	5.0
* **Beckman UniCel DxC Synchron**	291	5.32	0.12	4.6	8.51	-0.19	4.4	6.23	-0.07	4.1
* **Bio-Rad D-10**	207	5.29	0.09	2.8	8.94	0.24	2.5	6.45	0.15	2.7
* **Bio-Rad Variant II**	110	5.32	0.12	2.5	8.87	0.17	2.5	6.40	0.10	2.2
* **Bio-Rad Variant II Turbo**	146	5.28	0.08	2.7	8.74	0.04	2.2	6.38	0.08	2.2
* **Bio-Rad Variant II Turbo 2.0**	22	5.39	0.19	1.5	8.91	0.21	1.4	6.51	0.21	1.5
* **Roche Cobas c501**	161	5.40	0.20	3.3	8.55	-0.15	3.1	6.37	0.07	2.9
* **Roche Cobas Integra 400**	47	5.36	0.16	2.9	8.84	0.14	2.5	6.50	0.20	2.9
* **Roche Cobas Integra 800**	118	5.39	0.19	3.0	8.74	0.04	2.5	6.41	0.11	2.6
* **Roche/Hitachi Modular P**	17	5.29	0.09	4.3	8.4	-0.3	3.3	6.22	-0.08	3.6
* **Siemens Advia**	52	5.30	0.10	4.2	8.74	0.04	2.5	6.43	0.13	4.1
* **Siemens Advia New Reagent**	24	5.22	0.02	4.2	8.73	0.03	2.4	6.33	0.03	3.9
* **Siemens Advia Original Reagent**	13	5.42	0.22	3.3	8.83	0.13	2.5	6.55	0.25	2.7
* **Siemens DCA 2000/2000+**	75	5.29	0.09	2.6	8.71	0.01	3.2	6.45	0.15	2.6
* **Siemens DCA Vantage**	115	5.33	0.13	2.7	8.63	-0.07	2.8	6.40	0.10	2.2
* **Siemens Dimension ExL**	51	5.48	0.28	3.5	8.42	-0.28	3.7	6.33	0.03	3.1
* **Siemens Dimension RxL**	252	5.45	0.25	3.1	8.43	-0.27	3.4	6.34	0.04	3.1
* **Siemens Dimension Vista**	113	5.12	-0.08	3.2	8.75	0.05	2.1	6.21	-0.09	3.3
* **Siemens Dimension Xpand**	120	5.39	0.19	3.1	8.37	-0.33	3.7	6.28	-0.02	3.3
* **Tosoh A1c 2.2 Plus**	14	5.37	0.17	2.0	8.88	0.18	2.9	6.55	0.25	2.8
* **Tosoh G7 Auto HPLC**	216	5.38	0.18	2.0	8.81	0.11	1.7	6.48	0.18	1.6
* **Tosoh G8 Auto HPLC**	148	5.34	0.14	1.5	8.77	0.07	1.6	6.45	0.15	1.4
* **Trinity Biotech HPLC (Affinity)**	20	5.33	0.13	2.5	8.63	-0.07	3.1	6.38	0.08	2.4
* **Vitros 5,1 FS Chem System**	154	5.52	0.32	4.6	8.92	0.22	3.4	6.57	0.27	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 ≥ 0.4% HbA1c or CV ≥ 5% (except Bayer A1cNow bias)

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

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

- **Bias from the NGSP target and variability (±2SD) are shown in the table above and in figure 1 for each method. The shaded rectangle reflects the current CAP acceptance limit of ±8%. Other than the Bayer A1cNow[#] (see footnote above), the method-specific means were all within 0.4, 0.4 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. Only one method had a bias over 0.4% HbA1c (Beckman Synchron CX, -0.55% bias on the high level HbA1c sample).**
- **Method-specific, between-laboratory CV's ranged from 1.4% to 6.0%. Two methods (Tosoh G7 and G8) had CVs ≤2% for all 3 samples. Four methods showed CVs ≥5% for at least 1 sample (gray shading in table). One method (Beckman Synchron LX) had CVs >5% at all HbA1c levels. Approximately 94% of laboratories were using methods that had between-lab CVs <5.0% at all three HbA1c levels. The A1cNow is included here with the assumption that the EDTA interference does not affect assay imprecision.**
- **The current pass limit for the GH2 survey is ±8%. The overall pass rate for this survey was again over 95%; 95.3, 97.1, and 95.1% of labs passing for the low, mid and high samples, respectively. For individual methods, the lowest pass rate was 71.4% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-B 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.**
- **In 2011 and 2012, the pass limit for the GH2 survey will be decreased to ±7%. It is expected that the overall pass rate will fall slightly but will still be ≥93%. We hope to see methods continue to improve so that the pass rates will increase back to >95% with the ±7% pass limit.**
- **The overall CVs for all methods in all laboratories have decreased over the last few years. The overall CVs for the last two surveys are shown in Table 1. We are now approaching a total CV of 3.5% which is a worthy goal for 2011. There continue to be a few methods with either high CVs or high bias or both. But there are also many methods with continuously 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

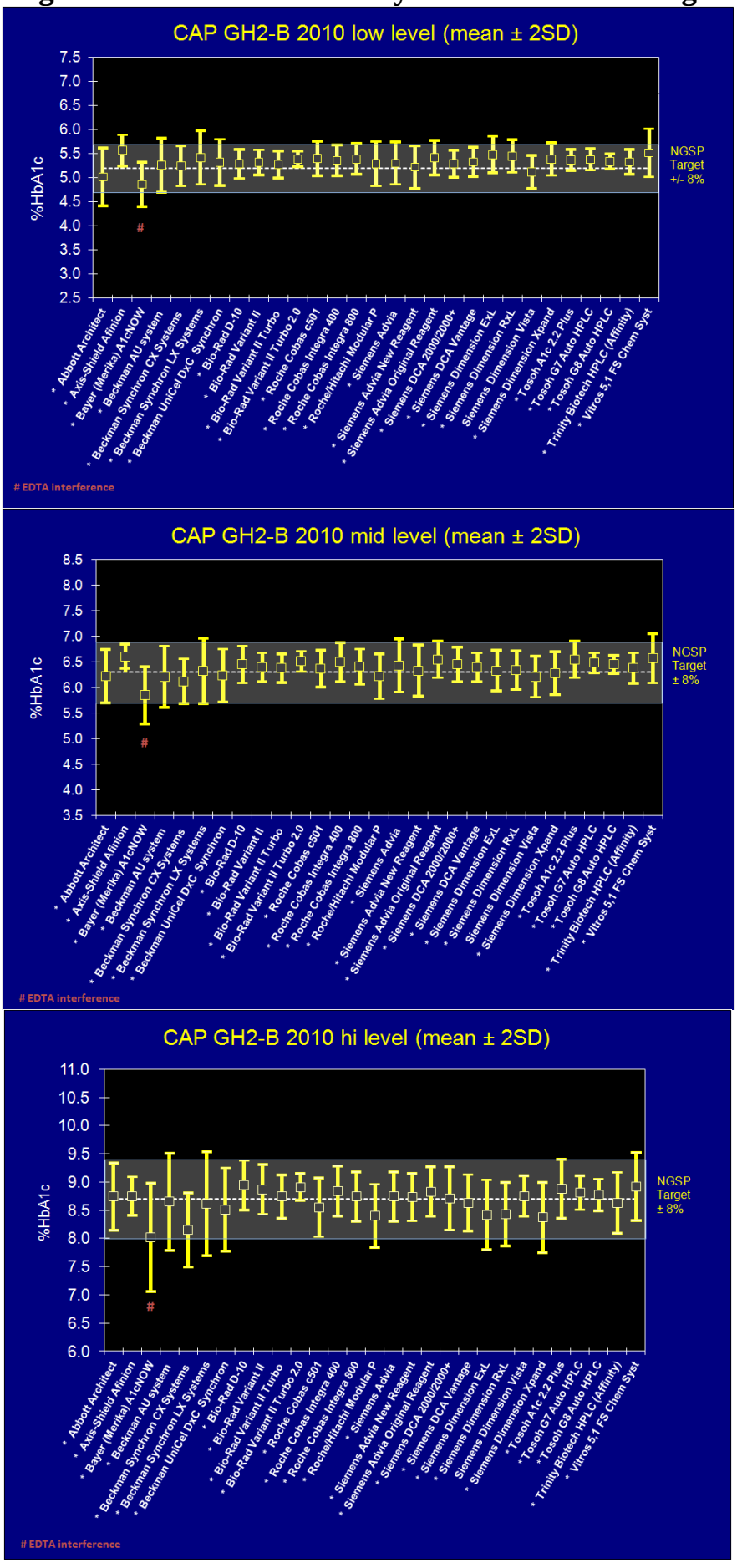

Table 1: Overall Variability for 2010 for all GH2 participants

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