College of American Pathologists (CAP) GH2 Survey Data:

(updated 5/13)

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 2013 are summarized below. The NGSP target or reference values are based on replicate analyses using seven NGSP certified secondary reference methods.

2013 GH2-A (fresh pooled samples)

		GH2-01			GH2-02			GH2-03		
[t] NGSP %HbA1c Reference Value (95% CI)		7.11 (7.05-7.17)			9.32 (9.26-9.38)			6.07 (6.-01-6.13)		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
* Abbott Architect c System	78	7.21	0.10	4.0	9.53	0.21	3.5	6.10	0.03	3.2
* Axis-Shield Afinion	24	7.14	0.03	3.3	9.02	-0.30	3.0	6.11	0.04	3.1
* Bayer A1cNOW[#]	16	6.37	-0.74	5.3	8.27	-1.05	4.1	5.40	-0.67	7.3
* Beckman AU systems	37	6.92	-0.19	5.5	9.16	-0.16	4.6	5.89	-0.18	5.0
* Beckman Synchron LX Systems	10	6.91	-0.20	3.5	9.41	0.09	2.2	6.29	0.22	8.2
* Beckman UniCel DxC Synchron	233	7.01	-0.10	3.5	9.45	0.13	3.6	6.06	-0.01	4.2
* Beckman UniCel DxC Synchron (orig)	143	7.01	-0.10	3.6	9.46	0.14	3.8	6.05	-0.02	4.2
* Bio-Rad D-10	210	7.16	0.05	2.7	9.41	0.09	2.6	6.14	0.07	2.6
* Bio-Rad Variant II	97	7.04	-0.07	2.1	9.37	0.05	2.2	5.97	-0.10	2.2
* Bio-Rad Variant II Turbo	152	7.16	0.05	2.6	9.43	0.11	2.0	6.05	-0.02	2.6
* Bio-Rad Variant II Turbo 2.0	51	7.12	0.01	2.2	9.35	0.03	2.3	6.11	0.04	2.6
* Roche Cobas c311	15	7.09	-0.02	3.3	9.44	0.12	2.9	6.03	-0.04	4.0
* Roche Cobas c500 series	237	6.95	-0.16	2.4	9.14	-0.18	2.9	6.06	-0.01	3.0
* Roche Cobas Integra 400	43	7.18	0.07	3.7	9.54	0.22	3.9	6.15	0.08	3.9
* Roche Cobas Integra 800	118	7.03	-0.08	1.8	9.35	0.03	2.0	6.08	0.01	2.1
* Siemens Advia Chemistry Systems	43	7.19	0.08	4.7	9.28	-0.04	3.8	6.33	0.26	4.4
* Siemens DCA 2000/2000+	39	7.08	-0.03	3.6	9.41	0.09	3.1	6.08	0.01	3.1
* Siemens DCA Vantage	235	6.99	-0.12	2.8	9.26	-0.06	3.0	6.05	-0.02	2.6
* Siemens Dimension ExL	131	7.14	0.03	2.2	9.44	0.12	2.6	6.29	0.22	2.9
* Siemens Dimension RxL	118	7.17	0.06	2.2	9.38	0.06	2.4	6.33	0.26	2.7
* Siemens Dimension Vista	204	7.34	0.23	2.8	9.49	0.17	2.9	6.25	0.18	3.3
* Siemens Dimension Xpand	74	7.11	0.00	2.3	9.41	0.09	2.1	6.22	0.15	3.4
* Tosoh G7 Auto HPLC	116	7.38	0.27	1.7	9.70	0.38	1.4	6.34	0.27	1.9
* Tosoh G8 Auto HPLC	259	7.34	0.23	1.3	9.67	0.35	1.2	6.31	0.24	1.4
* Trinity Biotech HPLC	20	7.15	0.04	2.5	9.23	-0.09	2.8	6.11	0.04	2.2
* Trinity Biotech Premier Hb9210	11	7.17	0.06	2.5	9.26	-0.06	2.4	6.17	0.10	2.5
* (Ortho Clin Diag) Vitros 5,1 FS, 4600, 5600 Chem System	176	6.92	-0.19	2.4	9.22	-0.10	2.3	5.83	-0.24	2.6

***** = 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 2013, based on data from the GH2-A 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 (fig 1) reflects the current CAP acceptance limit of ±6%. In**

addition to the Bayer A1cNow[#] (see footnote above), the method-specific biases were over 0.30 for only 2 methods (high level only): Tosoh G7 and G8.

- **Method-specific, between-laboratory CV's ranged from 1.2% to 8.2%. All but 2 methods (Beckman AU and Beckman Synchron LX) had CVs below 5% for all three levels. More than 98% of laboratories were using methods that had between-lab CVs <5.0% at all three HbA1c levels; about 50% of laboratories are using methods with CVs <3% at all three HbA1c levels.**
- **The current pass limit for the GH2 survey is ±6%. The overall pass rate for this survey was 93.4, 95.3 and 94.3% of labs passing for the low, mid and high samples, respectively. For individual methods, the lowest pass rate was 63.6% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-A 2013). 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 2013A survey's CVs were still above 3.5% at one level; 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 (see table above). But there are also many methods that show consistent good performance.**
- **The expanded uncertainty (k=2, shown as the 95% confidence interval) of the NGSP reference value assignment has been added to the above table.**

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

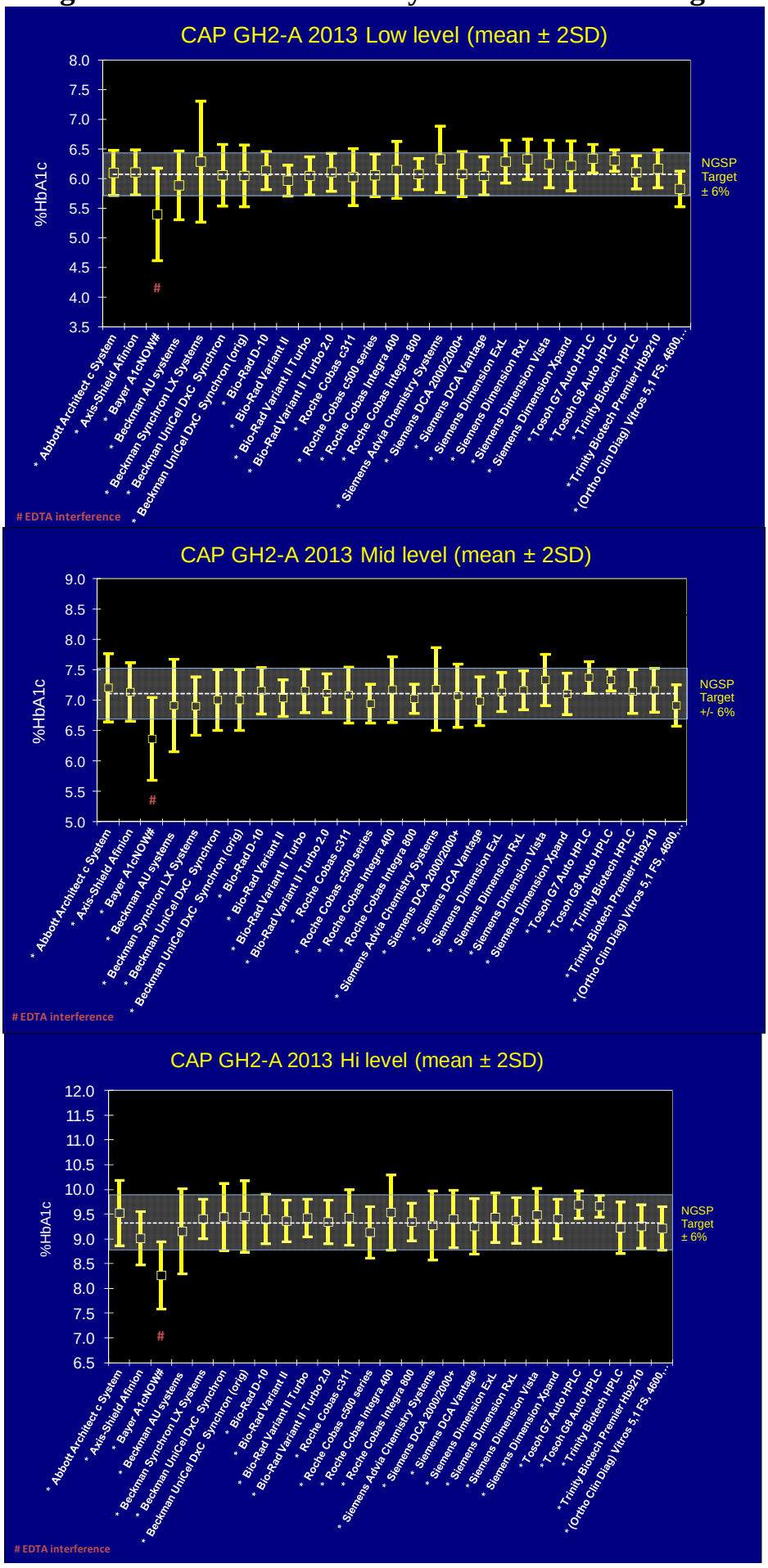

Table 1: Overall Variability for 2010-2013 for all GH2 participants

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
A 2013	01	2816	7.1	7.12	0.25	3.5
	02	2829	9.3	9.39	0.31	3.3
	03	2840	6.1	6.13	0.24	3.9