

College of American Pathologists (CAP) Survey Data:

(updated 5/08)

The American Diabetes Association (ADA) recommends that laboratories use only GHB assay methods that have been NGSP certified and report results as “%HbA1c” or “%HbA1c equivalents”. The ADA also recommends that all laboratories performing GHB 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 2008 are summarized below. Results from laboratories reporting HbA1c or equivalent and those reporting total GHB are included, although results from methods reporting total GHB cannot be directly compared to NGSP Reference values. The NGSP target or reference values are based on replicate analyses using four NGSP certified secondary reference methods.

2008 GH2-A (fresh pooled samples)

* = NGSP certified at the time of the survey

		GH2-01		GH2-02		GH2-03	
NGSP Reference Value ^t		13.0		5.3		8.8	
	no. labs	Median	%CV	Median	%CV	Median	%CV
Methods reporting HbA1c (or equivalent)							
* Abbott Architect/Aeroseet	49	12.5	5.1	5.1	4.2	9.2	5.1
* Beckman Synchron System	369	13.2	4.6	5.3	4.8	8.7	4.5
* Bio-Rad D-10	177	13.2	2.4	5.3	3.1	9.0	2.3
* Bio-Rad Variant A1c	10	12.7	2.5	5.1	4.1	8.7	1.3
* Bio-Rad Variant II A1c	175	13.4	2.5	5.3	3.5	9.2	2.4
* Bio-Rad Variant II Turbo A1c	128	13.5	3.3	5.5	2.1	9.3	2.7
* Dade Behring Dimension	574	12.9	4.4	5.6	3.1	8.6	3
* Metrika A1cNOW [#]	19	11.9	5.6	4.9	3.7	8.2	6.6
* Olympus AU system	30	12.8	6	5.2	3.5	8.9	5.4
* Primus HPLC (affinity)	24	12.8	3.2	5.3	2.8	8.6	3
* Roche Cobas c501	45	12.3	3.7	5.4	3.2	8.6	3.9
* Roche Cobas Integra	146	12.7	3.9	5.4	3	8.9	3.1
* Roche Cobas Integra Gen.2	90	12.5	3.6	5.4	3.2	8.8	2.9
* Roche/Hitachi (Tina Quant II)	41	13.2	4.5	5.4	3.6	8.6	4.2
* Siemens Advia 1650/2400	34	13.6	7.1	5.6	4.2	9.0	3
* Siemens DCA 2000	187	13.7	4	5.2	2.8	8.5	2.9
* Tosoh A1c 2.2 Plus	130	13.9	3.9	5.5	4.5	9.4	3.4
* Tosoh G7 Auto HPLC	263	13.7	3.8	5.4	1.9	9.2	2.6
* Vitros 5,1 FS Chem Syst	98	12.9	5.9	5.3	2.9	8.6	3.7

		GH2-01		GH2-02		GH2-03	
NGSP Reference Value ^t		13.0		5.3		8.8	
	no. labs	Median	%CV	Median	%CV	Median	%CV
^s Methods reporting Total GHB							
Primus	16	19.2	5.1	6.1	5.7	11.8	6.0

^t Assigned as the mean value of 6 replicate analyses over two days using 3 NGSP certified secondary reference methods.

^s Methods reporting Total GHB are not considered NGSP certified even though the same method reporting HbA1c is NGSP certified.

[#]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

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

In 2008, based on data from the GH2-A survey:

- Over 99% of laboratories reported results as HbA1c or equivalent and used a certified method; there were only 16 laboratories (<1%) still reporting total GHB.
- Bias from the NGSP target and variability ($\pm 2SD$) are shown in *figure 1* for each method.
- For NGSP certified methods, other than the Metrika A1cNow[#] (see footnote above), the method-specific medians were all within 0.3, 0.6 and 0.9% HbA1c of NGSP targets at the low, mid and high HbA1c levels, respectively (table above). The Tosoh 2.2 Plus continues to show the largest bias (0.9%) for the high level HbA1c specimen
- Method-specific, between-laboratory CV's ranged from 1.3% to 7.1%. The Metrika A1c Now, Abbott Architect/Aeroset, and Olympus AU system showed between-laboratory CVs >5% at two of three levels. All certified methods show CVs of <5% for the low HbA1c level and more than 90% of laboratories were using methods that had between-lab CVs $\leq 5.0\%$ at all three HbA1c levels
- This is the third GH2 survey using an accuracy based target (NGSP); peer group means are no longer used for grading the GH2 survey. The acceptable limit for this survey is $\pm 12\%$ of the target value; the acceptable limit for grading will be reduced in future surveys. The overall pass rate ranged from 96.7 to 98.5%, depending on the HbA1c level. For individual methods, the lowest pass rate was 80% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-A 2008). Methods with low bias and low CVs will have the highest pass rates and conversely, methods with either high bias or high CVs or both will have the lowest pass rates.
- *Figure 2* examines the bias (A) and CV (B) trends for the 2006 through 2008A surveys for the 10 most used methods (methods with >100 users on the 2008A survey) for the mid-level sample. Note that the variability is somewhat dependent on the exact HbA1c level; the target %HbA1c for the mid level was lowest for the 2006B survey (7.1%) and highest for the 2007B survey (9.2%). Unfortunately, there is no obvious decrease in overall bias between methods; the mean bias varies from -0.3% to +0.6%. CVs (B) have remained below 5% with most method CVs below 4% for the mid-level HbA1c samples.

Figure 1

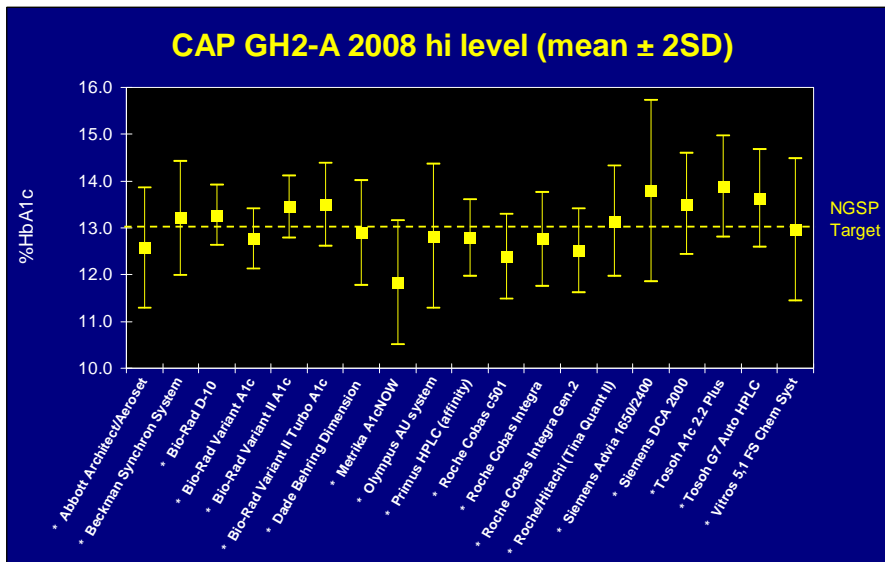
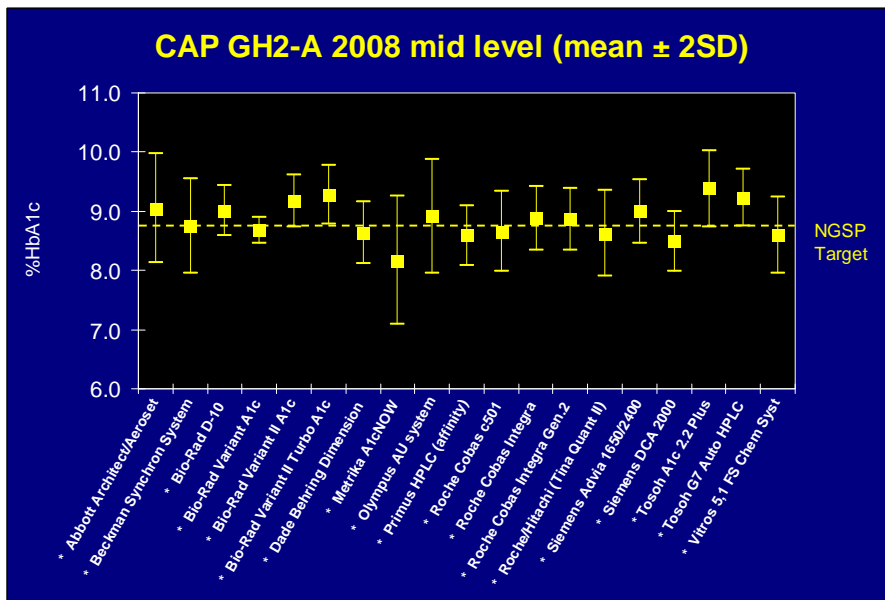
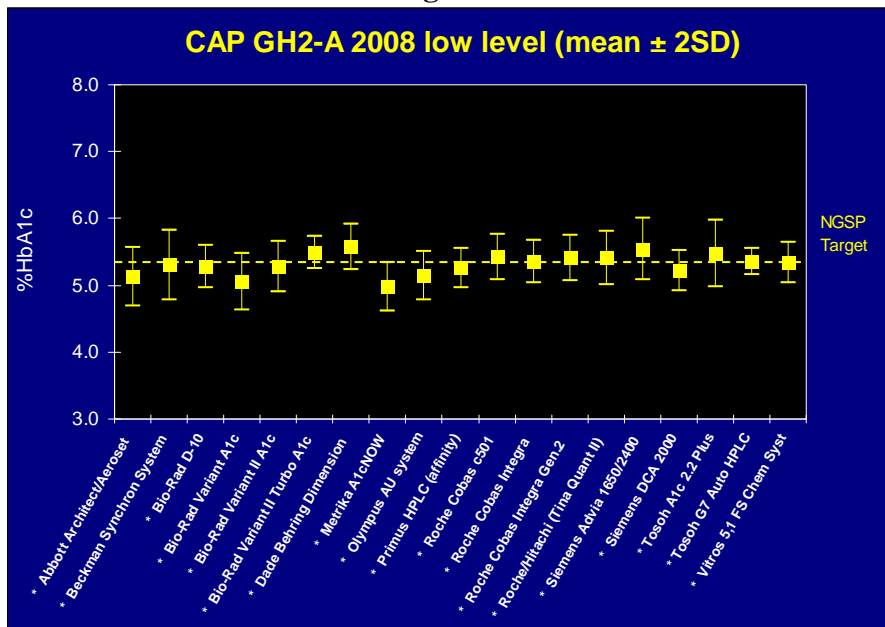


Figure 2A:

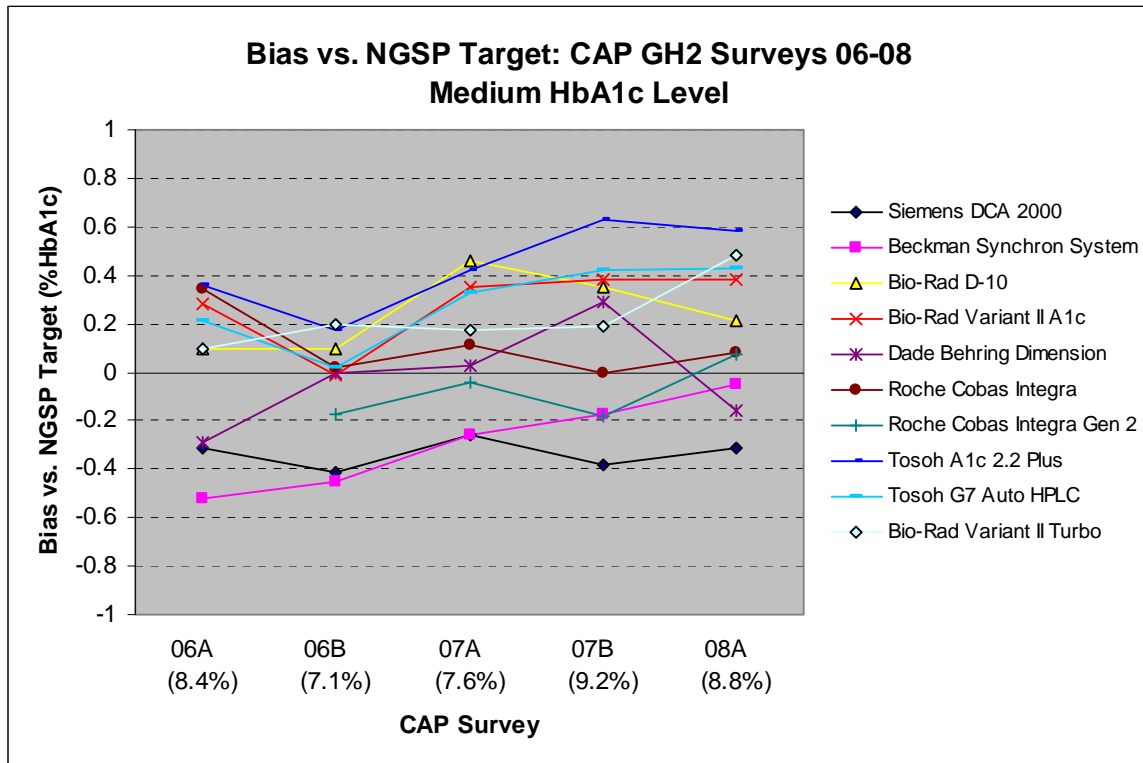
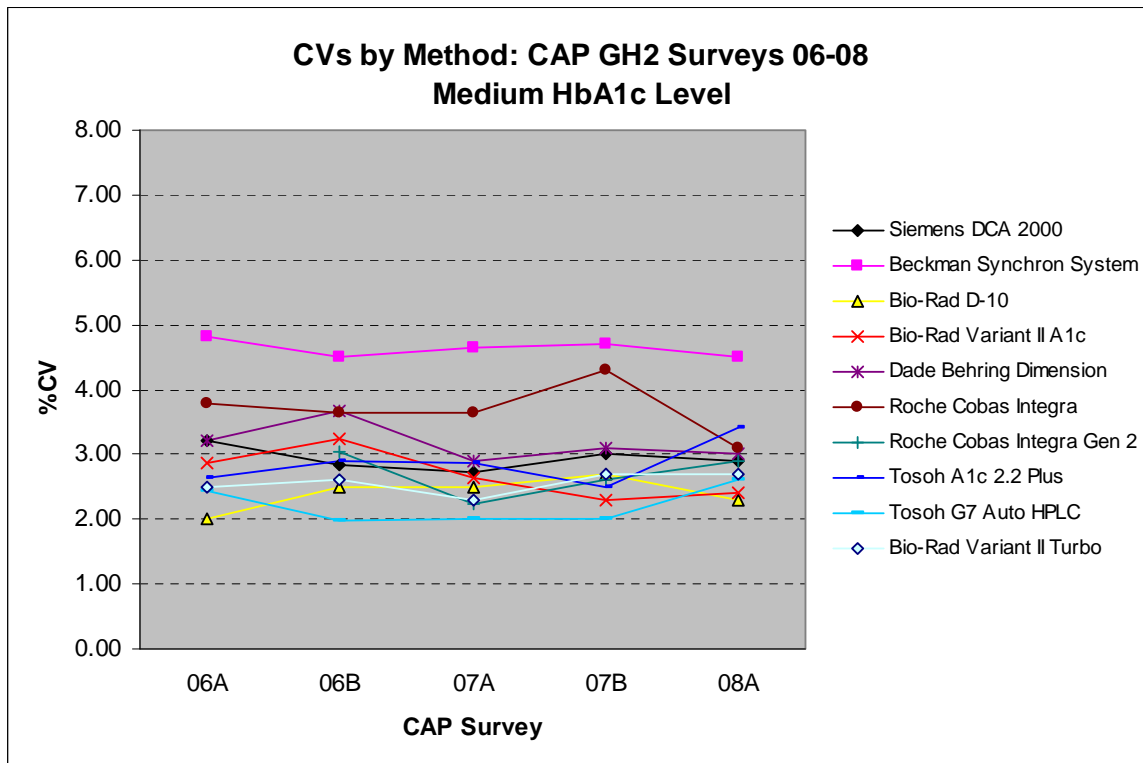


Figure 2B:



NOTE: A method must have a total imprecision $\leq 4\%$ (NCCLS EP5) in order to be NGSP certified. However, the NGSP evaluates precision in one laboratory (usually 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 700) 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 laboratorians review not only the certification status of GHB methods but also their performance in the CAP survey over time (a good indication of field performance) when selecting or evaluating GHB assay methods.