

# College of American Pathologists (CAP) Survey Data:

(updated 5/06)

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 2006 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.

## 2006 GH2-A (fresh pooled samples)

\* = NGSP certified at the time of the survey

		GH2-01		GH2-02		GH2-03	
NGSP Reference Value <sup>t</sup>		10.7		5.30		8.40	
	no. labs	Median	%CV	Median	%CV	Median	%CV
<b>Methods reporting HbA1c (or equivalent)</b>							
Abbott Architect	24	10.9	6.4	4.8	8.8	8.3	5.3
* Bayer Advia	24	9.9	6.9	5.2	3.5	8.0	5.8
* Bayer DCA 2000	156	10.4	3.0	4.9	4.6	8.1	3.2
* Beckman Synchron System	291	10.6	4.8	5.2	5.4	7.9	4.8
* Bio-Rad D-10	106	10.9	2.1	5.3	2.9	8.5	2.0
* Bio-Rad Diastat	15	10.0	6.1	5.0	5.9	8.0	5.5
* Bio-Rad Variant A1c	20	10.5	1.7	5.2	1.3	8.4	1.9
* Bio-Rad Variant II A1c	254	11.2	2.8	5.3	2.6	8.7	2.9
* Bio-Rad Variant II Turbo A1c	40	10.9	2.4	5.3	2.3	8.4	2.5
* Dade Behring Dimension	490	10.5	3.1	5.6	3.6	8.1	3.2
* Metrika A1cNOW	15	10.4	8.1	5.3	6.3	8.2	7.6
* Olympus AU system	22	11.2	4.0	5.5	3.9	8.9	5.5
* Primus HPLC (affinity)	25	10.9	3.2	5.1	3.5	8.4	3.3
* Roche Cobas Integra	248	11.1	4.0	5.5	3.6	8.7	3.7
* Roche/Hitachi (Tina Quant II)	62	10.6	3.3	5.4	4.5	8.0	4.7
* Tosoh A1c 2.2 Plus	193	11.6	2.9	5.4	2.9	8.8	2.6
* Tosoh G7 Auto HPLC	196	11.3	2.1	5.2	2.3	8.6	2.5
* Vitros 5,1 FS Chem Syst	26	11.0	4.5	5.7	3.7	8.2	3.7

		GH2-04		GH2-05		GH2-06	
NGSP Reference Value <sup>t</sup>		10.7		5.30		8.40	
	no. labs	Median	%CV	Median	%CV	Median	%CV
<sup>s</sup> Methods reporting Total GHB							
Bio-Rad Variant	10	13.6	2.7	5.6	8.0	10.2	5.9
Primus	9	15.2	-	6.0	-	11.2	-

<sup>t</sup> Assigned as the mean value of 6 replicate analyses over two days using 5 NGSP certified secondary reference methods.

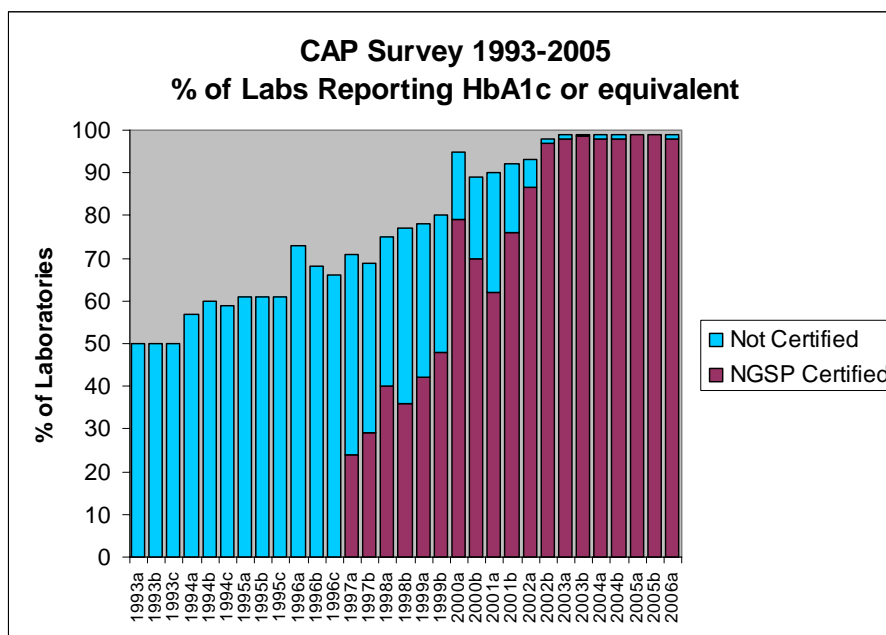
<sup>s</sup> Methods reporting Total GHB are not considered NGSP certified even though the same method reporting HbA1c is NGSP certified.

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

In 2006, based on data from the GH2-B survey:

- 99% of laboratories reported results as HbA1c or equivalent and 98% used a certified method (figure 1).

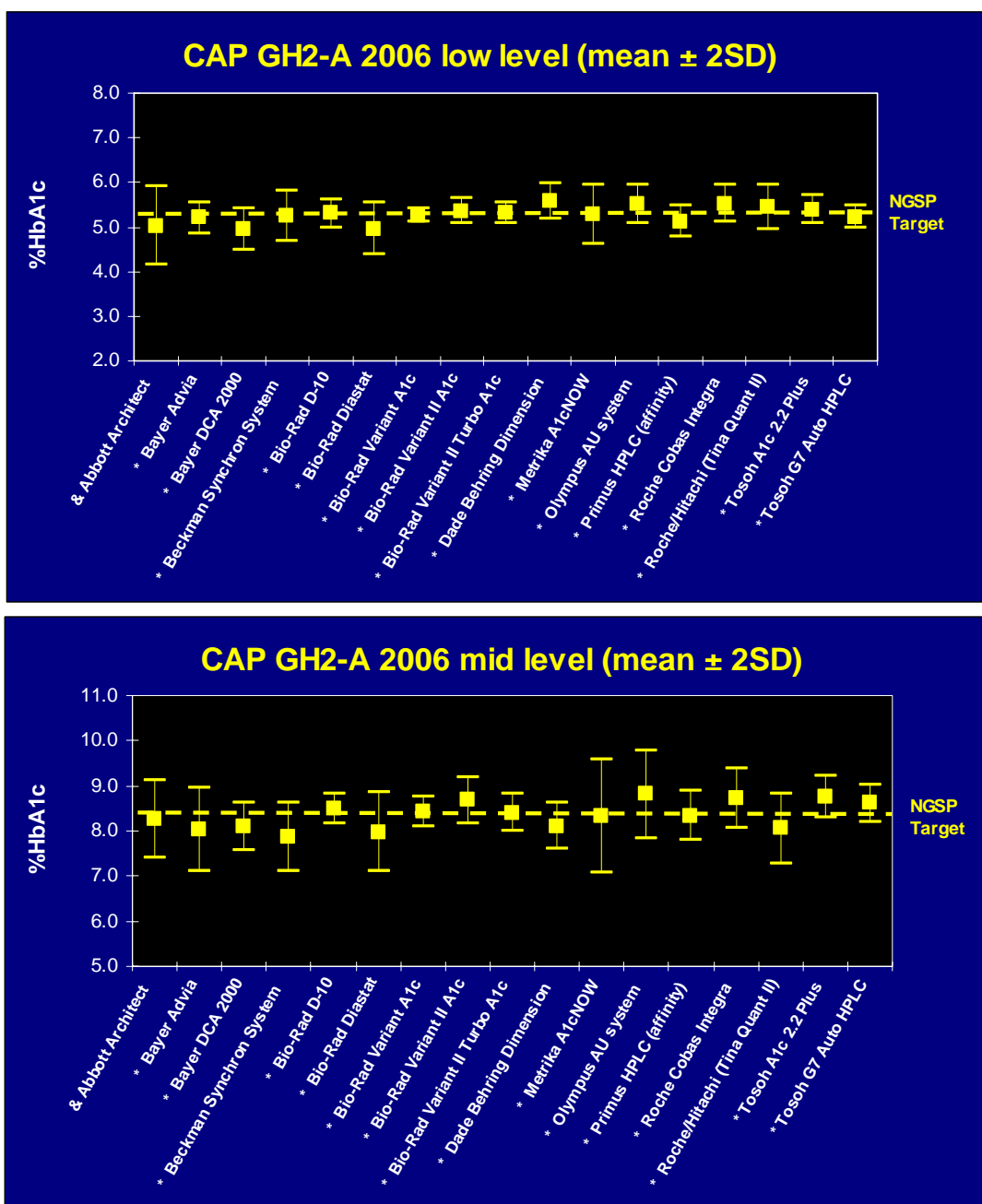
Figure 1

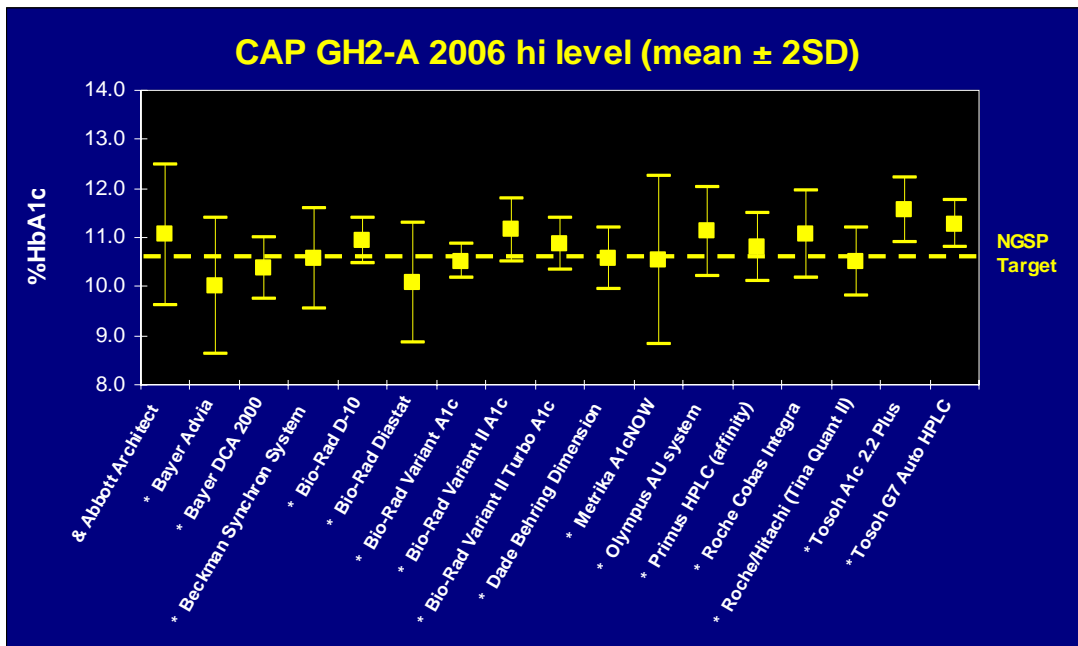


- For NGSP certified methods, the method-specific medians were all within 0.4, 0.5 and 0.9 % HbA1c of NGSP targets at the low, mid and high HbA1c levels, respectively (table above). MOST (75-85%) were within 0.2% HbA1c for the low HbA1c specimen, 0.4% HbA1c for the mid level specimen and within 0.5% for the high level.
- Method-specific, between-laboratory CV's ranged from 1.3% to 8.1% for certified methods. 71% of certified methods had between-lab CVs  $\leq 5.0\%$  at all HbA1c levels (table above).
- Although the Metrika A1c Now showed very little bias from the NGSP target, this method had the highest between-laboratory CVs (8.1%, 6.3%, 7.6%).
- Several methods, all of which are HPLC, showed between-lab CVs  $\leq 3.0\%$  at all HbA1c levels; the Bio-Rad D-10, Variant, Variant II and Variant II Turbo, and the Tosoh 2.2 Plus and G7.

- Bias from the NGSP target and variability ( $\pm 2SD$ ) are shown in *figure 2* for each method (\* indicates NGSP certified).
- As in the 2004 and 2005 GH-B surveys, each participating laboratory was evaluated against the NGSP target values with an acceptable limit equal to  $\pm 7\%$  of the target value. For now, this “dual grade” is still for educational purposes only. However, at some point in the near future, the accuracy comparison demonstrated by the “dual grade” will be used for grading; peer group means will no longer be used (Sacks, Chemistry Resource Committee, CAP GH2-B 2005 participant summary report discussion). Once again, each laboratory has been instructed to “assess the accuracy and precision of its instrument, and if necessary, initiate appropriate actions”. The overall pass rate was about 85% for all HbA1c levels. Pass rates varied from 42 to 100% depending on the specific method and specimen.

Figure 2





*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.*