

# College of American Pathologists (CAP) Survey Data:

(updated 12/05)

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 second survey of 2005 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.

## 2005 GH2-B (fresh pooled samples)

\* = NGSP certified at the time of the survey

		GH2-04		GH2-05		GH2-06	
NGSP Reference Value <sup>t</sup>		11.70		9.20		5.30	
	no. labs	Median	%CV	Median	%CV	Median	%CV
<b>Methods reporting HbA1c (or equivalent)</b>							
* Abbott Architect <sup>&amp;</sup>	16	12.3	7.0	9.6	6.8	5.3	2.8
* Bayer Advia	19	10.5	5.9	8.5	4.9	5.1	4.1
* Bayer DCA 2000	163	11.3	3.0	8.9	2.9	4.9	4.1
* Beckman Synchron System	300	11.7	4.3	8.9	4.2	5.3	5.0
* Bio-Rad D-10	98	11.9	2.4	9.5	2.4	5.3	3.8
* Bio-Rad Diastat	25	11.3	5.8	8.7	5.5	4.9	4.8
* Bio-Rad Variant A1c	28	11.3	3.7	9.1	3.9	5.0	4.3
* Bio-Rad Variant II A1c	286	12.0	3.1	9.6	3.2	5.3	3.4
* Bio-Rad Variant II Turbo A1c	29	11.7	2.3	9.3	2.3	5.3	3.1
* Dade Behring Dimension	444	11.5	3.7	8.9	3.3	5.6	3.6
* Metrika A1cNOW	39	11.3	7.0	9.1	7.0	5.1	6.7
* Olympus AU system	25	12.1	5.8	9.7	5.9	5.5	4.5
* Primus HPLC (affinity)	26	11.8	3.2	9.1	3.2	5.0	3.7
* Roche Cobas Integra	267	12.1	4.0	9.6	4.0	5.4	3.7
* Roche/Hitachi (Tina Quant II)	69	11.6	3.9	8.8	4.1	5.3	5.8
* Tosoh A1c 2.2 Plus	204	12.5	2.8	9.9	2.9	5.4	3.1
* Tosoh G7 Auto HPLC	175	12.2	2.1	9.6	2.0	5.2	2.6
Vitros 5,1 FS Chem Syst	9	11.2	-	8.9	-	5.3	-

		GH2-04		GH2-05		GH2-06	
NGSP Reference Value <sup>t</sup>		11.70		9.20		5.30	
	no. labs	Median	%CV	Median	%CV	Median	%CV
<sup>s</sup> Methods reporting Total GHB							
Bio-Rad Variant	8	15.0	-	11.2	-	5.2	-
Primus	9	17.2	-	12.6	-	5.6	-

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

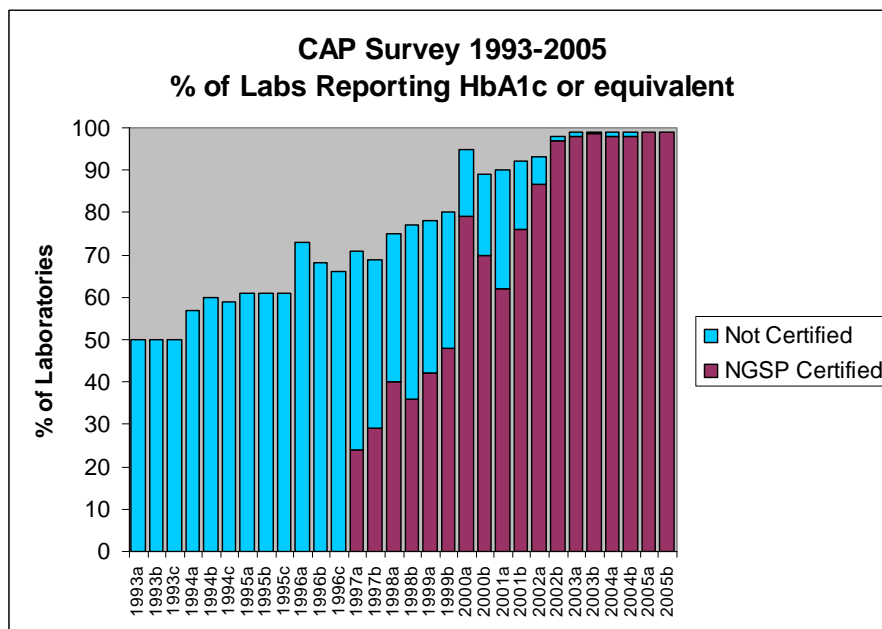
<sup>&</sup> The Abbott instrument listed can be considered NGSP certified if they use the Multigent reagents certified by Seradyn on these instruments.

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

In 2005, based on data from the GH2-B survey:

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

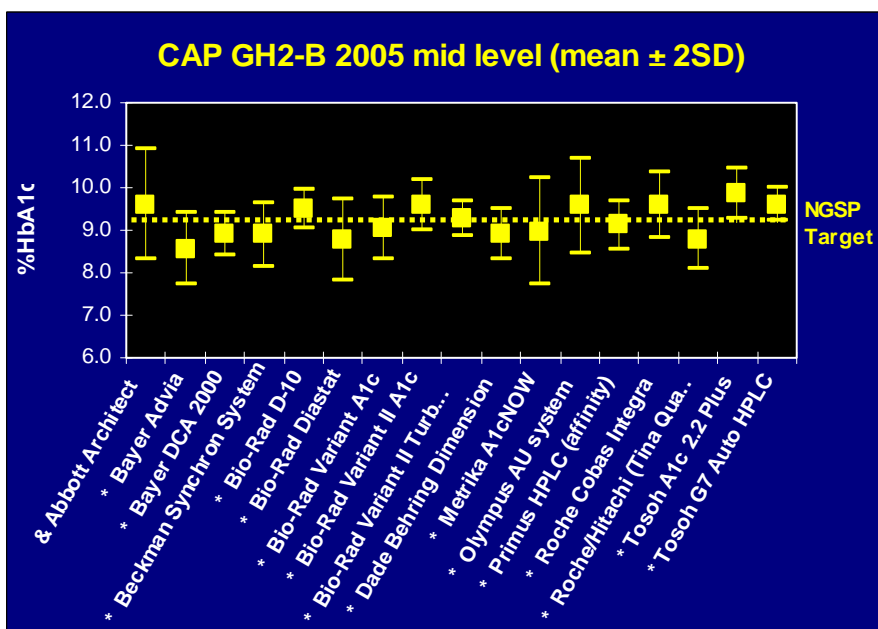
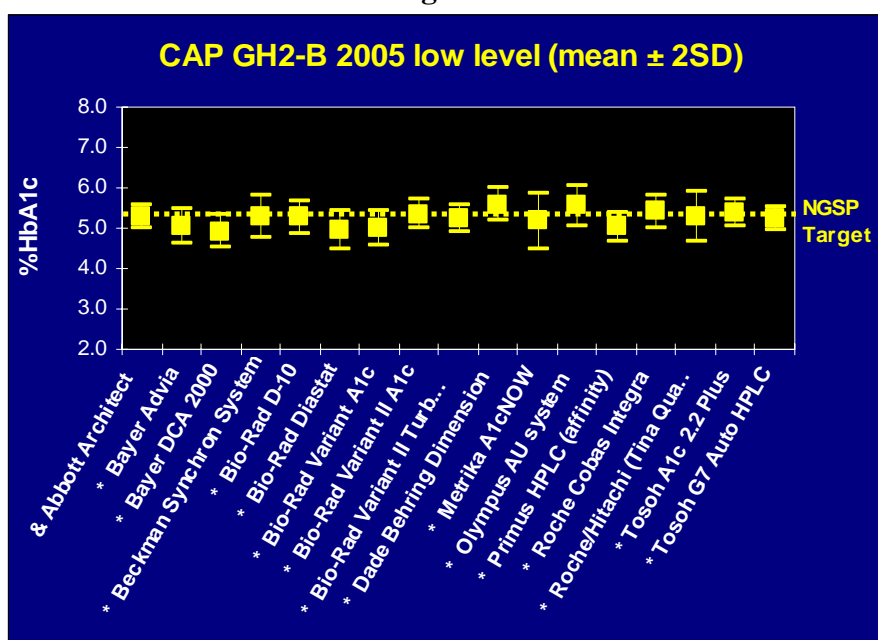
**Figure 1**

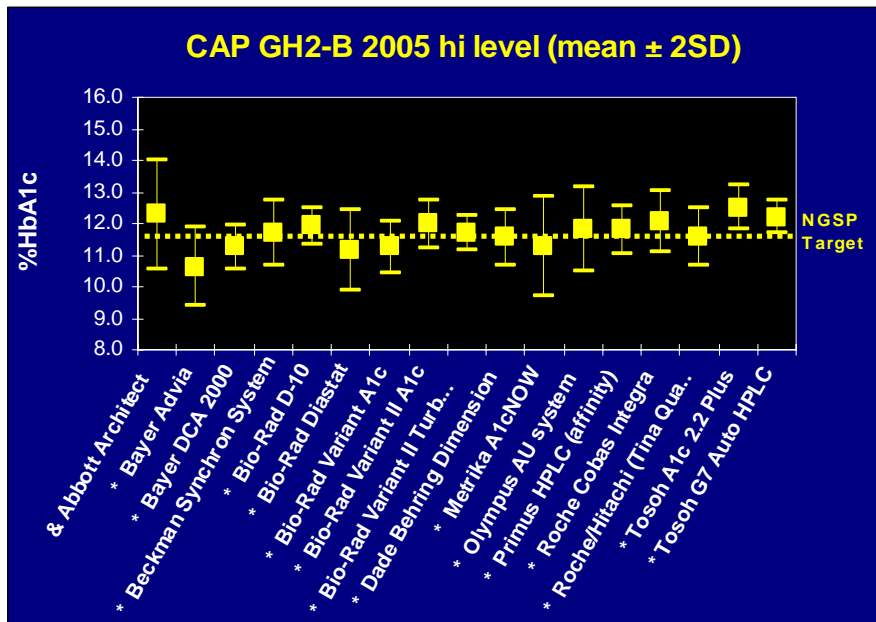


- For NGSP certified methods, the method-specific medians were all within 0.4, 0.7 and 1.2 % HbA1c of NGSP targets at the low, mid and high HbA1c levels, respectively (table above). MOST (75-85%) were within 0.3% HbA1c for the low HbA1c specimen, 0.4% HbA1c for the mid level specimen and within 0.5% for the high level.
- Method-specific, between-laboratory CV's ranged from 2% to 7% for certified methods. 67% of certified methods had between-lab CVs ≤5.0% at all HbA1c levels (table above).
- The Abbott Architect and Metrika A1c Now had the highest between-laboratory CVs (7%, 6.8%, 2.8% for Abbott Architect; 7%, 7%, 6.7% for Metrika).

- Only the Tosoh G7 showed between-lab CVs  $\leq 3.0\%$  at all HbA1c levels; the Bayer DCA2000, Bio-Rad D-10, Bio-Rad Variant II Turbo, and Tosoh 2.2 Plus showed between-lab CVs  $\leq 3.0\%$  at the middle and high HbA1c levels.
- Bias from the NGSP target and variability ( $\pm 2SD$ ) are shown in *figure 2* for each method.
- As in the 2004 GH-B survey, 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 for educational purposes only. However, beginning with the GH2-A Survey in 2006, 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 ranged from 86.1 to 89.1% depending on the HbA1c level. Some methods were able to achieve 100% pass rates, i.e. all laboratories using that method were within  $\pm 7\%$  of the NGSP targets.

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.*