# College of American Pathologists (CAP) Survey Data:

(updated 12/06)

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 second 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-B (fresh pooled samples)

***** = NGSP certified at the time of the survey

| | | GH2-04 | | GH2-05 | | GH2-06 | |
|---|---|---|---|---|---|---|---|
| **NGSP Reference Value[t]** | | **7.1** | | **7.0** | | **11.7** | |
| | no. labs | **Median** | %CV | **Median** | %CV | **Median** | %CV |
| **Methods reporting HbA1c (or equivalent)** | | | | | | | |
| *** Abbott Architect** | 28 | **6.5** | 7.4 | **6.6** | 7.7 | **11.6** | 5.0 |
| *** Bayer Advia** | 30 | **6.9** | 5.7 | **6.9** | 5.6 | **11.0** | 6.7 |
| *** Bayer DCA 2000** | 159 | **6.7** | 2.9 | **6.7** | 2.7 | **11.4** | 3.5 |
| *** Beckman Synchron System** | 310 | **6.6** | 4.4 | **6.6** | 4.3 | **11.4** | 4.7 |
| *** Bio-Rad D-10** | 130 | **7.2** | 2.6 | **7.2** | 2.6 | **12.3** | 2.4 |
| *** Bio-Rad Diastat** | 13 | **6.9** | 5.1 | **6.8** | 5.5 | **11.8** | 3.6 |
| *** Bio-Rad Variant A1c** | 23 | **6.9** | 2.9 | **6.9** | 3.1 | **11.6** | 3.6 |
| *** Bio-Rad Variant II A1c** | 239 | **7.1** | 3.2 | **7.1** | 3.0 | **12.2** | 3.0 |
| *** Bio-Rad Variant II Turbo A1c** | 54 | **6.9** | 2.6 | **6.9** | 2.2 | **12.0** | 2.6 |
| *** Dade Behring Dimension** | 494 | **7.1** | 3.7 | **7.1** | 3.6 | **11.5** | 3.7 |
| *** Metrika A1cNOW** | 18 | **6.7** | 7.0 | **6.7** | 7.7 | **11.4** | 7.5 |
| *** Olympus AU system** | 26 | **7.3** | 4.3 | **7.2** | 4.3 | **12.4** | 4.5 |
| *** Primus HPLC (affinity)** | 27 | **6.5** | 4.0 | **6.5** | 3.9 | **11.5** | 3.2 |
| *** Roche Cobas Integra** | 253 | **7.1** | 3.7 | **7.1** | 3.7 | **12.1** | 3.9 |
| *** Roche Cobas Integra Gen.2** | 20 | **6.9** | 3.1 | **7.0** | 2.8 | **11.6** | 4.1 |
| *** Roche/Hitachi (Tina Quant II)** | 53 | **6.8** | 5.1 | **6.8** | 4.8 | **11.5** | 3.8 |
| *** Tosoh A1c 2.2 Plus** | 181 | **7.3** | 2.9 | **7.3** | 2.9 | **12.6** | 3.1 |
| *** Tosoh G7 Auto HPLC** | 200 | **7.1** | 1.9 | **7.1** | 1.8 | **12.3** | 1.5 |
| *** Vitros 5,1 FS Chem Syst** | 39 | **6.7** | 2.7 | **6.7** | 3.9 | **11.4** | 4.5 |

| | | GH2-04 | | GH2-05 | | GH2-06 | |
|---|---|---|---|---|---|---|---|
| **NGSP Reference Value[t]** | | **10.7** | | **5.30** | | **8.40** | |
| | no. labs | **Median** | %CV | **Median** | %CV | **Median** | %CV |
| **[$]Methods reporting Total GHB** | | | | | | | |
| **Bio-Rad Variant** | 9 | **7.6** | - | **7.6** | - | **14.8** | - |
| **Primus** | 6 | **8.3** | - | **8.3** | - | **16.9** | - |

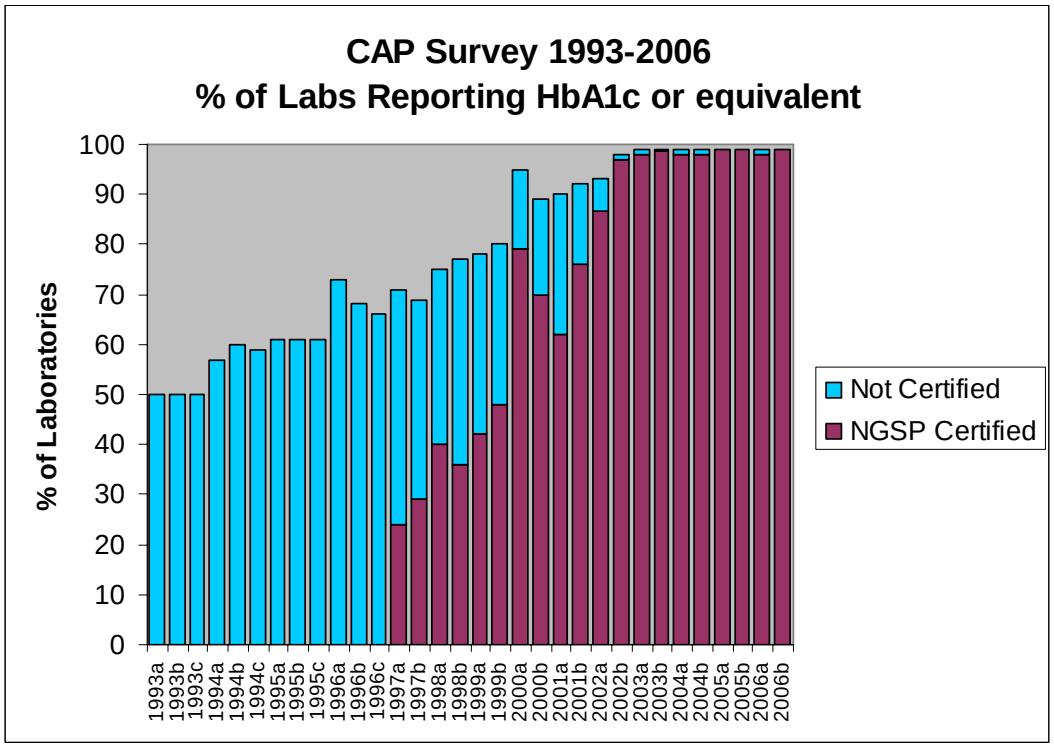
[t] Assigned as the mean value of 6 replicate analyses over two days using 5 NGSP certified secondary reference methods.
[$] Methods reporting Total GHB are not considered NGSP certified even though the same method reporting HbA1c *is* NGSP certified.

**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 99% used a certified method *(figure 1)*.**

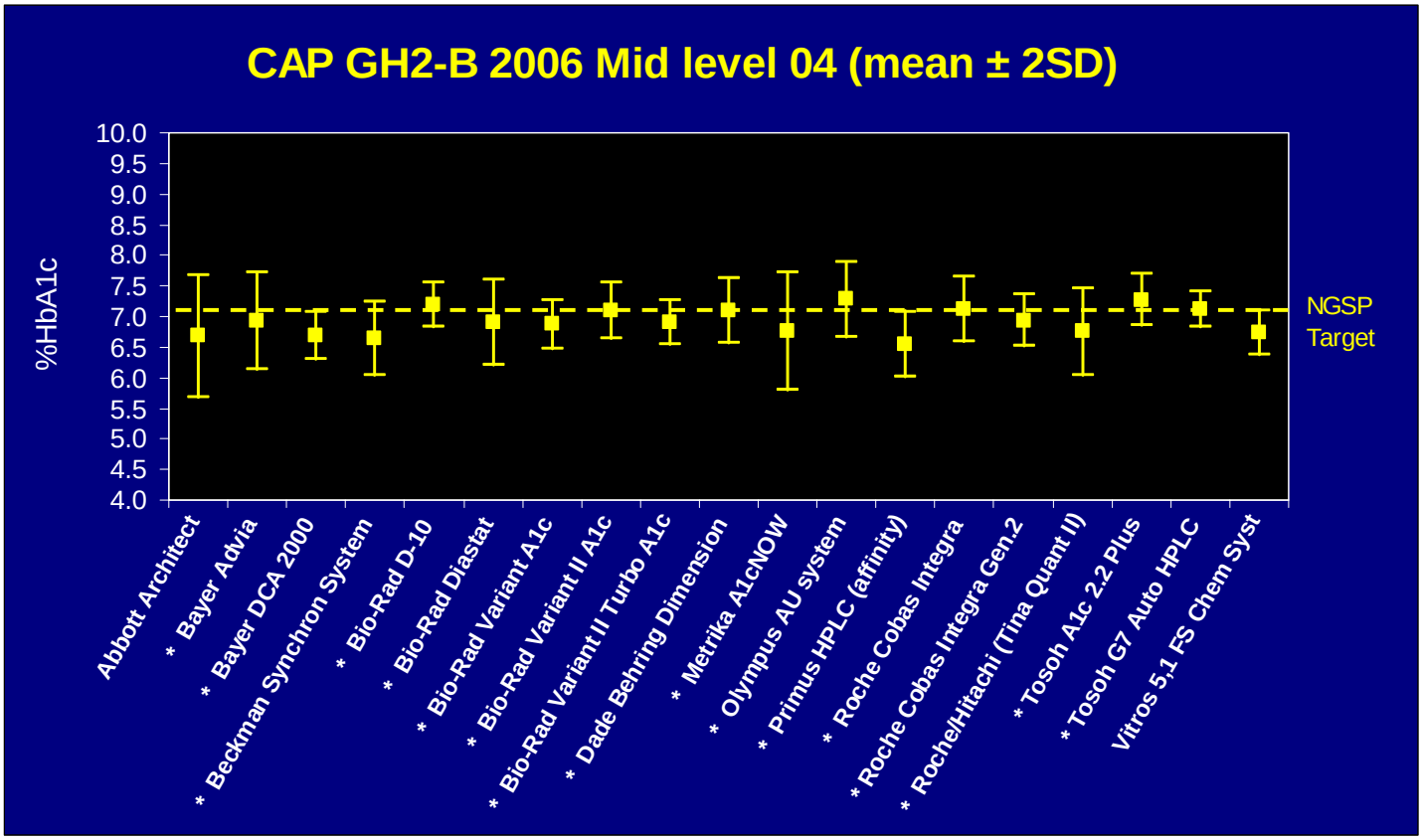
**Figure 1**

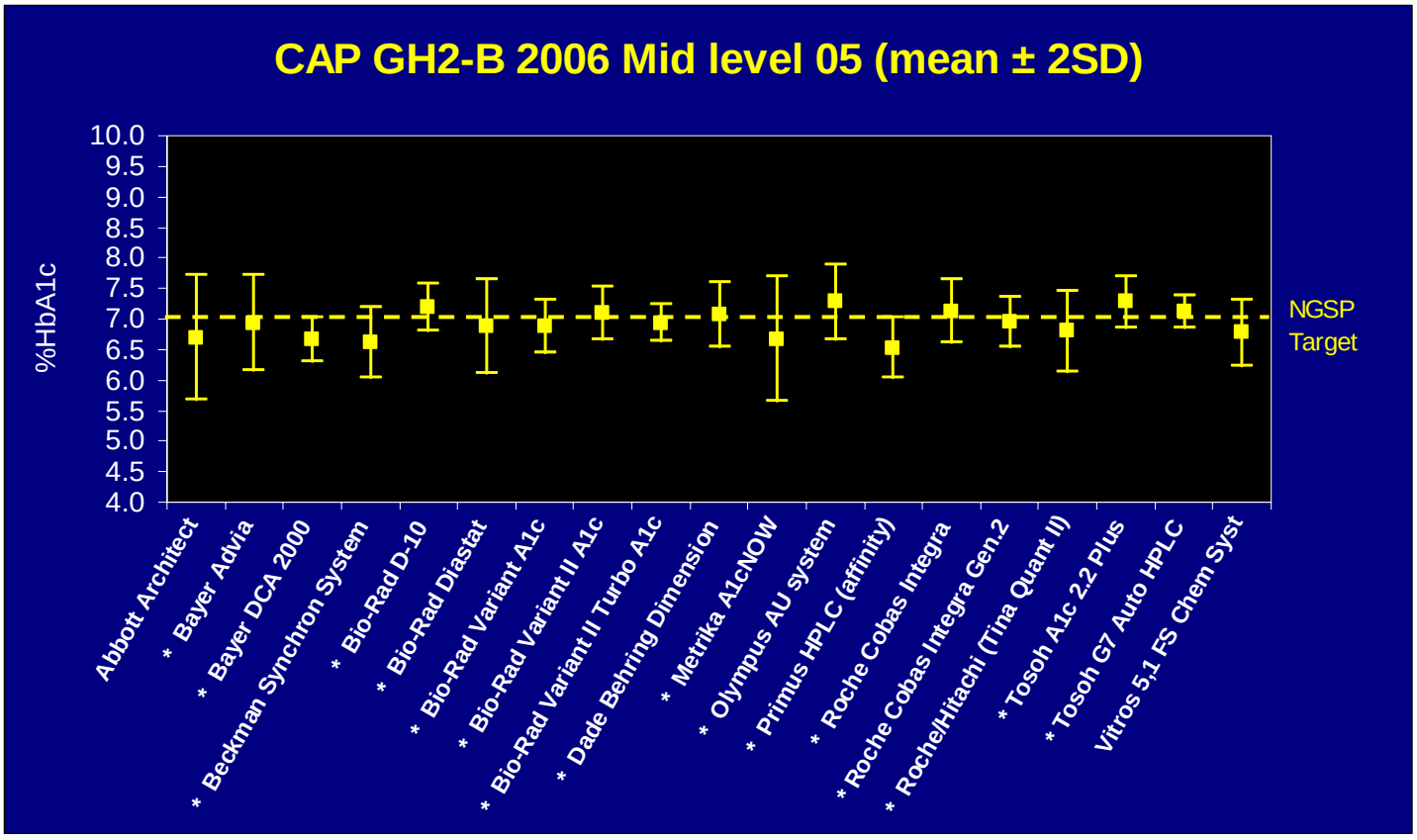


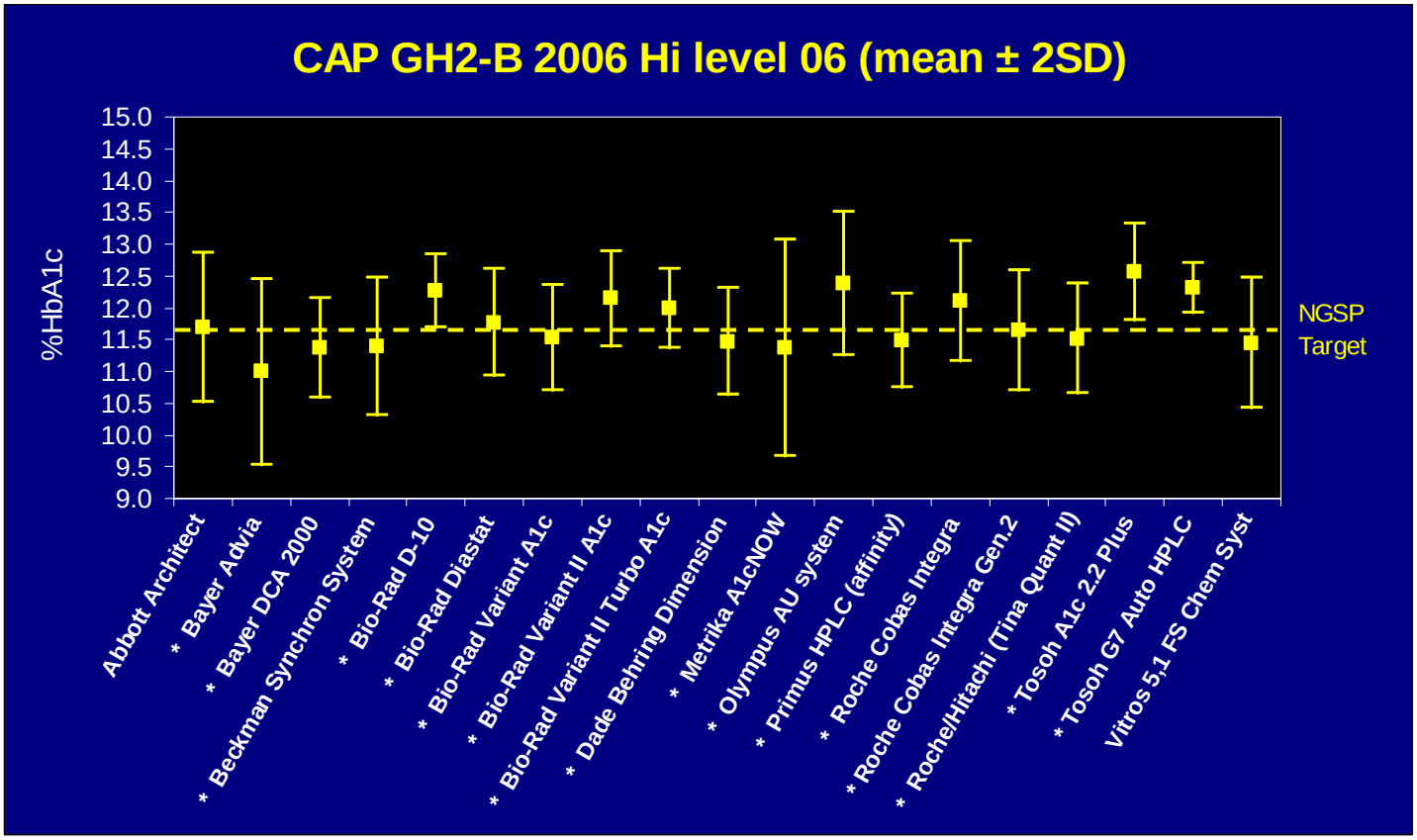

- **Samples GH2-04 and GH2-05 appear to be the same sample, although this wasn't mentioned in the CAP participant summary discussion.**
- **For NGSP certified methods, the method-specific medians were all within 0.6, 0.5 and 0.9 % HbA1c of NGSP targets at the mid, mid and high HbA1c levels, respectively (table above). MOST (>75%) were within 0.4% HbA1c for the mid level specimens and within 0.5% for the high level.**

- **Method-specific, between-laboratory CV's ranged from 1.5% to 7.7% for certified methods. 74% of certified methods had between-lab CVs ≤5.0% at all HbA1c levels (table above).**
- **The Abbott Architect and Metrika A1c Now showed the highest between-laboratory CVs (>7%).**
- **The Bio-Rad D-10, Bio-Rad Variant II Turbo and Tosoh G7 showed CVs below 3% for all samples.**
- **Bias from the NGSP target and variability (±2SD) are shown in *figure 2* for each method.**
- **As in the 2004 and 2005 GH-B surveys, each participating laboratory was evaluated against the NGSP target values. In 2004, 2005, and the first survey of 2006, the acceptable limit was ±7% of the target value. For the current survey, the acceptable limit is ±15% of the target value. The overall pass rate was about 99% for all HbA1c levels using the ±15% limits. For now, this "dual grade" is still for educational purposes only. However, according to the 2006B participant summary discussion, beginning with the 1st survey of 2007, the accuracy comparison demonstrated by the "dual grade" will be used for grading; peer group means will no longer be used (Miller, Chemistry Resource Committee, CAP GH2-B 2006). "Accuracy based grading provides important information to a laboratory because it evaluates the combination of bias and imprecision (total error) that correctly identifies the laboratories and methods that have discrepant results that are not adequate for management of diabetic patients. All methods are expected to produce equivalent results that are standardized to the NGSP; consequently evaluating all results using an accuracy based criterion consistent with clinical performance requirements maximizes the value of the survey to participants."**

**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.*