

College of American Pathologists (CAP) Survey Data:

(updated 5/07)

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 2007 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.

2007 GH2-A (fresh pooled samples)

* = NGSP certified at the time of the survey

		GH2-01		GH2-02		GH2-03	
NGSP Reference Value ^t		5.4		11.6		7.6	
	no. labs	Median	%CV	Median	%CV	Median	%CV
Methods reporting HbA1c (or equivalent)							
* Abbott Architect	47	5.0	5.0	11.2	3.9	7.4	4.1
* Bayer Advia	33	5.5	4.2	11.3	4.9	7.7	5.2
* Bayer DCA 2000	227	5.2	2.9	11.5	4.8	7.4	2.7
* Beckman Synchron System	385	5.3	4.6	11.7	5.4	7.3	4.6
* Bio-Rad D-10	169	5.5	2.7	12.6	2.3	8.1	2.5
* Bio-Rad Diastat	11	5.2	3.5	11.8	4.4	7.3	3.7
* Bio-Rad Variant A1c	17	5.2	2.6	11.5	2.2	7.5	3.7
* Bio-Rad Variant II A1c	253	5.4	3.4	12.3	2.5	7.9	2.6
* Bio-Rad Variant II Turbo A1c	95	5.4	2.7	12.0	2.6	7.8	2.3
* Dade Behring Dimension	593	5.8	3.1	11.3	3.5	7.6	2.8
* Metrika A1cNOW	23	5.3	6.1	11.7	6.3	7.4	7.7
* Olympus AU system	30	5.6	6.2	12.2	6.1	8.2	5.5
* Pointe Scientific	5	5.0	-	11.0	-	7.5	-
* Primus HPLC (affinity)	36	5.3	2.7	11.7	2.5	7.6	2.3
* Roche cobas c501	6	5.8	-	11.4	-	7.5	-
* Roche Cobas Integra	239	5.5	3.4	11.8	3.7	7.7	3.6
* Roche Cobas Integra Gen.2	72	5.5	3.3	11.7	2.8	7.5	2.3
* Roche/Hitachi (Tina Quant II)	63	5.5	5.2	11.8	4.2	7.5	3.5
* Tosoh A1c 2.2 Plus	186	5.4	3.5	12.4	2.7	8.0	2.9
* Tosoh G7 Auto HPLC	261	5.4	2.4	12.3	1.8	7.9	2.0
* Vitros 5,1 FS Chem Syst	66	5.7	3.6	12.3	4.4	7.7	4.0

		GH2-01		GH2-02		GH2-03	
NGSP Reference Value ^t		5.4		11.6		7.6	
	no. labs	Median	%CV	Median	%CV	Median	%CV
^s Methods reporting Total GHB							
Bio-Rad Variant	10	5.4	6.5	14.1	4.2	8.8	3.9
Primus	15	6.2	4.3	17.1	2.3	10.0	2.9

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

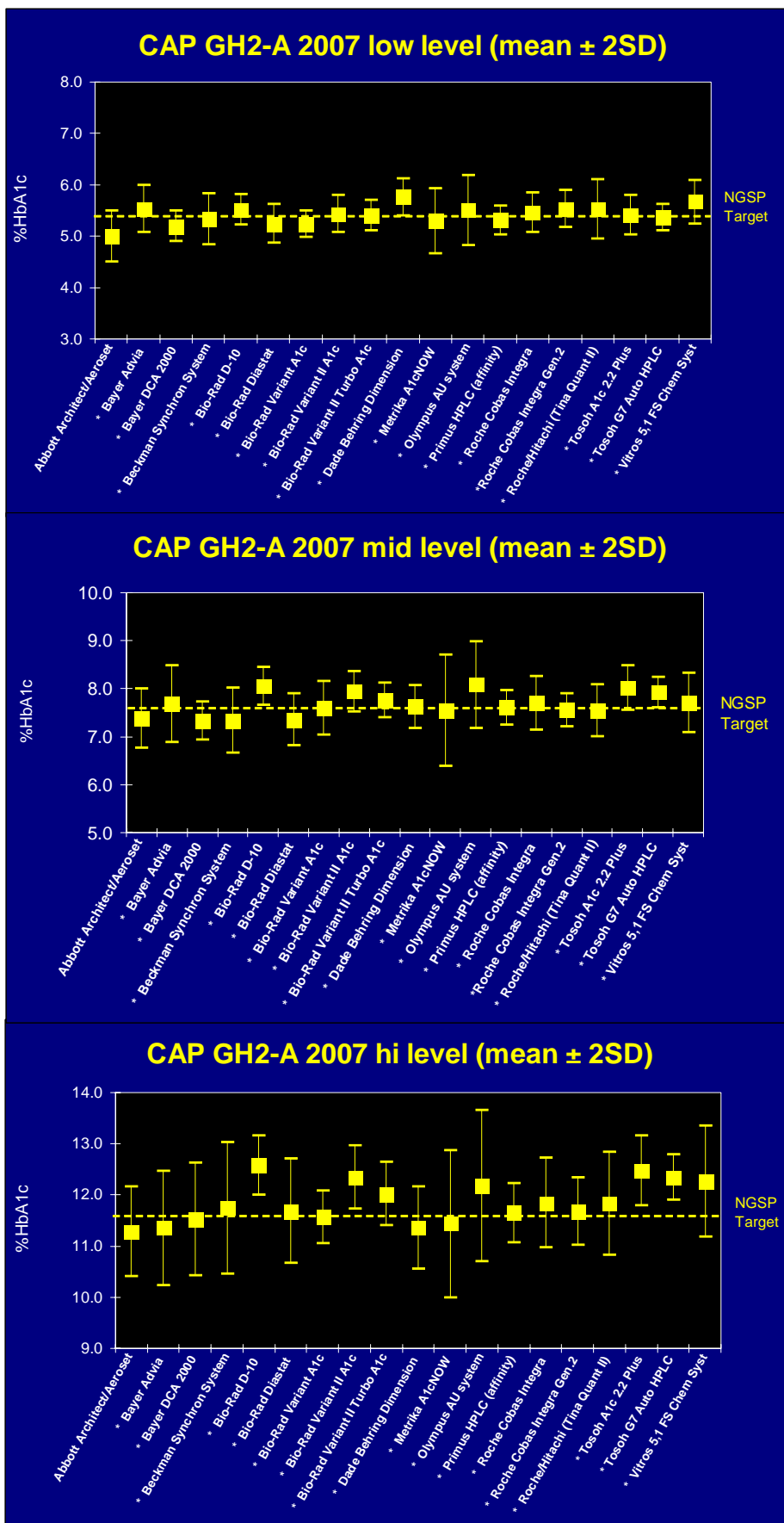
^s Methods reporting Total GHB are not considered NGSP certified even though the same method reporting HbA1c is NGSP certified.

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

In 2007, based on data from the GH2-A survey:

- 99% of laboratories reported results as HbA1c or equivalent and 99% used a certified method; there are still a few laboratories reporting total GHB.
- For NGSP certified methods, the method-specific medians were all within 0.4, 0.6 and 1.0 % HbA1c of NGSP targets at the low, mid and high HbA1c levels, respectively (table above). MOST methods (>75%) were within 0.2% HbA1c for the low level specimens, 0.3% HbA1c for the mid level and within 0.4% HbA1c 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 $\leq 5.0\%$ at all three HbA1c levels (table above).
- The Metrika A1c Now and the Olympus AU Systems showed between-laboratory CVs >5% at all three levels. The Beckman Synchron and Roche /Hitachi each showed a CV >5% at one level.
- The Bio-Rad D-10, Bio-Rad Variant II Turbo, Primus HPLC (affinity) and Tosoh G7 showed CVs below 3% for all samples.
- Bias from the NGSP target and variability ($\pm 2SD$) are shown in *figure 1* for each method.
- This is the first GH2 survey using an accuracy based target (NGSP); peer group means will no longer be used for grading the GH2 survey. Currently the acceptable limit is $\pm 15\%$ of the target value, e.g., results for a sample with a HbA1c value of 6.6% would have an acceptable range of 5.6% to 7.6% HbA1c. This criterion was selected to be consistent with the performance requirements for NGSP method certification, and to give a pass rate similar to that with the former peer bgroup grading scheme. "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" (Miller, Chemistry Resource Committee, CAP GH2-B 2006).

Figure 1



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.