

College of American Pathologists (CAP) Survey Data:

(updated 5/05)

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 first 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-A (fresh pooled samples)

* = NGSP certified at the time of the survey

		GH2-01		GH2-02		GH2-03	
NGSP Reference Value ^t		7.4		12.0		7.4	
	no. labs	Median	%CV	Median	%CV	Median	%CV
Methods reporting HbA1c (or equivalent)							
& Abbott Aeroset	5	7.5	-	13.0	-	7.4	-
& Abbott Architect	8	7.1	-	11.8	-	7.1	-
* Bayer Advia	18	7.1	6.6	11.0	9.7	7.0	6.6
* Bayer DCA 2000	174	7.3	3.1	11.7	3.0	7.2	2.9
* Beckman Synchron System	279	7.0	4.8	12.1	5.1	7.0	4.5
* Bio-Rad D-10	75	7.7	2.4	12.7	2.1	7.7	2.2
* Bio-Rad Diastat	29	7.3	4.6	12.3	4.6	7.3	5.0
* Bio-Rad Variant A1c	32	7.4	3.0	11.8	3.8	7.4	3.1
* Bio-Rad Variant II A1c	298	7.6	3.1	12.4	3.0	7.6	3.2
* Bio-Rad Variant II Turbo A1c	17	7.6	3.1	12.4	3.3	7.6	2.6
* Dade Behring Dimension	419	7.6	3.4	11.8	2.8	7.5	3.3
* Metrika A1cNOW	12	7.2	7.8	11.9	5.1	7.2	7.7
* Olympus AU system	15	7.3	6.0	12.1	7.8	7.3	6.6
* Primus HPLC (affinity)	22	7.3	2.8	12.4	2.2	7.3	2.8
* Primus Nycocard	5	7.6	-	11.7	-	7.6	-
* Roche Cobas Integra	266	7.6	3.5	12.6	4.3	7.7	3.7
* Roche/Hitachi (Tina Quant II)	81	7.0	3.7	11.9	4.6	7.0	3.7
* Tosoh A1c 2.2 Plus	212	7.8	2.6	12.9	2.6	7.8	2.8
* Tosoh G7 Auto HPLC	169	7.6	1.9	12.5	2.0	7.6	1.8

		GH2-01		GH2-02		GH2-03	
NGSP Reference Value ^t		7.4		12.0		7.4	
	no. labs	Median	%CV	Median	%CV	Median	%CV
^s Methods reporting Total GHB							
Bio-Rad Variant	13	8.5	3.7	15.8	3.2	8.6	3.9
Primus	8	9.6	-	18.2	-	9.6	-

^t Assigned as the mean value of 6 replicate analyses over two days using 4 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.

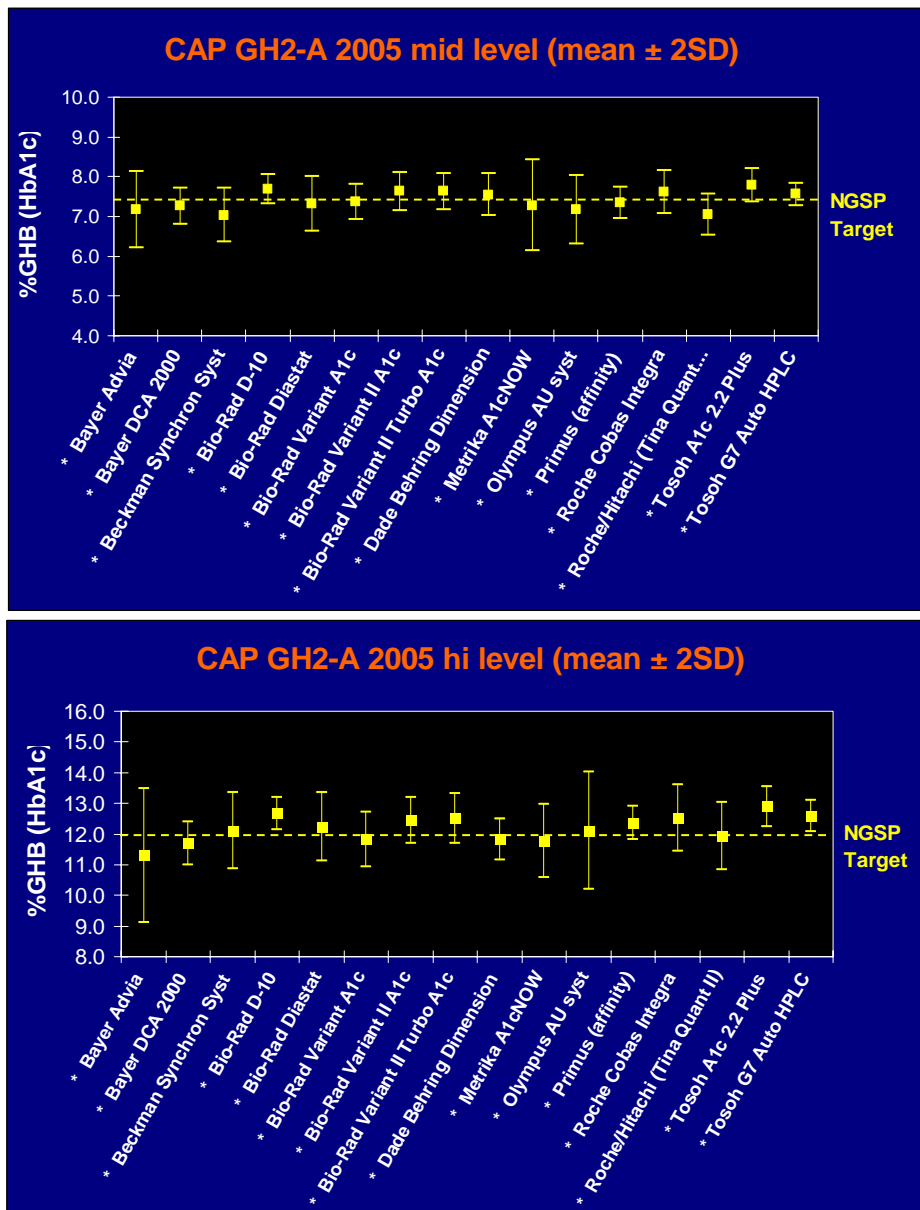
[&] The Abbott instruments listed can be considered NGSP certified if they use the Multigent reagents certified by Seradyn on these instruments.

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

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

- **Note: In this survey, specimens GH2-01 and GH2-03 were the same specimen. Therefore, only data for specimens -01 and -02 are included in the analysis below.**
- **99% of laboratories reported results as HbA1c or equivalent and used a certified method ([figure 1](#)).**
- **For NGSP certified methods, the method-specific medians were all within 0.4% and 1.0 % HbA1c of NGSP targets at the low/mid and high HbA1c levels, respectively (table above). MOST (75-85%) were within 0.2-0.3% HbA1c for the low HbA1c specimen and within 0.5% for the high level).**
- **Method-specific, between-laboratory CV's ranged from 1.9% to 9.7% for certified methods. MOST (80-85%) certified methods had between-lab CVs <5.0% at all HbA1c levels (table above).**
- **The Metrika A1c Now, Bayer Advia 1650/2400, and Olympus AU systems had the highest imprecision.**
- **Four methods (Bio-Rad D-10, Primus HPLC, Tosoh G7, Tosoh A1c 2.2 Plus) showed between-lab CVs ≤3.0% at both HbA1c levels.**
- **Bias from the NGSP target and variability (±2SD) are shown in [figure 2](#) for each method.**

Figure 2



In this survey, specimens GH2-01 and GH2-03 were replicate specimens filled from the same pool of material. This allowed calculation of within-laboratory variability for all laboratories and divided by method and method type.

- Greater than 95% of laboratories had an absolute bias of less than 0.5% HbA1c between replicates [figure 3](#).
- The Bio-Rad Variant and Variant II Turbo, Tosoh G7, and Primus HPLC showed the lowest bias between replicates [figure 4](#) and, in general, HPLC (both ion-exchange and boronate affinity) methods demonstrated lower variability compared to immunoassay methods.

Figure 3

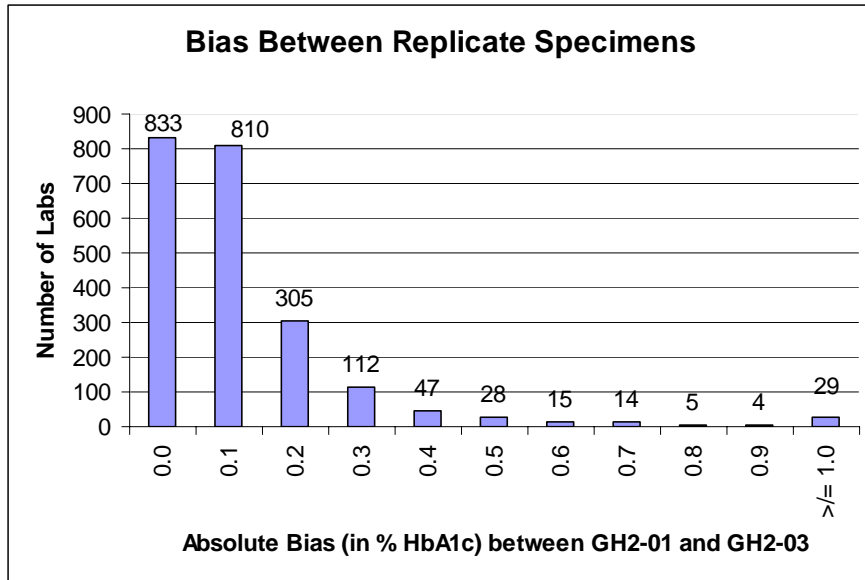
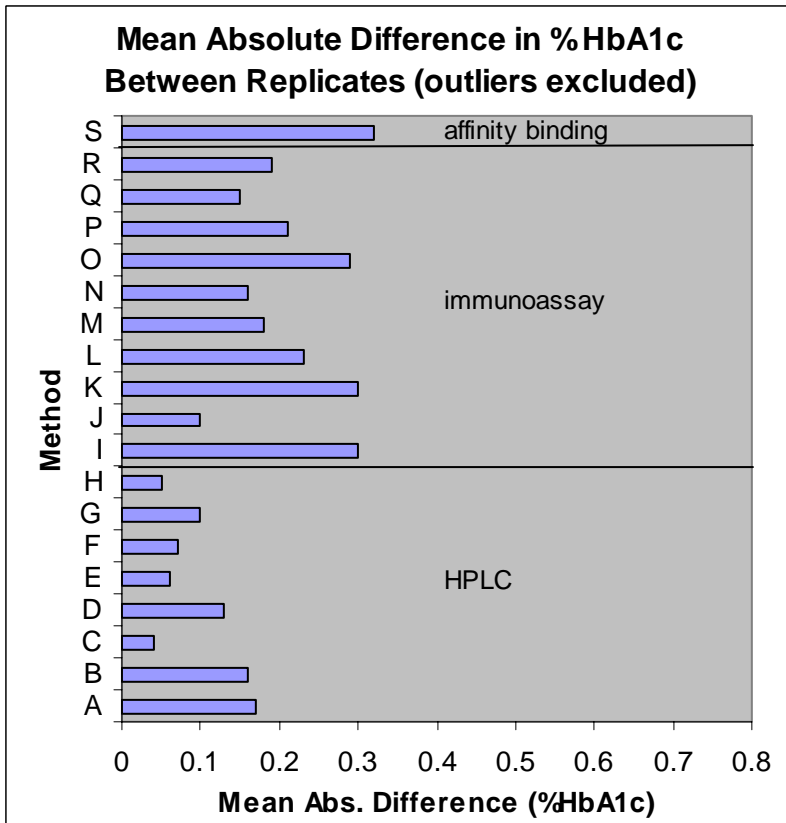


Figure 4



Legend:

Method	Code	Method type
BIO-RAD D-10	A	HPLC
BIO-RAD DIASTAT	B	HPLC
BIO-RAD VARIANT	C	HPLC
BIO-RAD VARIANT II	D	HPLC
BIO-RAD VARIANT II TURBO	E	HPLC
PRIMUS HPLC (AFFINITY)	F	HPLC
TOSOH A1C 2.2 PLUS	G	HPLC
TOSOH G7 AUTO HPLC	H	HPLC
ABBOTT AEROSSET	I	immunoassay
ABBOTT ARCHITECT	J	immunoassay
BAYER ADVIA 1650/2400	K	immunoassay
BAYER DCA 2000/2000+	L	immunoassay
BECKMAN SYNCHRON	M	immunoassay
DADE BEHRG DIMENSION	N	immunoassay
METRIKA A1cNOW	O	immunoassay
OLYMPUS AU SYSTEMS	P	immunoassay
ROCHE COBAS INTEGRA	Q	immunoassay
ROCHE/HITACHI	R	immunoassay
PRIMUS NYCOCARD	S	affinity binding

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.