College of American Pathologists (CAP) Survey Data:

(updated 1/08)

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.

2007 GH2-B (fresh pooled samples)

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

		GH2-04		GH2-05		GH2-06	
NGSP Reference Value[t]		**9.2**		**11.1**		**6.2**	
	no. labs	**Median**	%CV	**Median**	%CV	**Median**	%CV
Methods reporting HbA1c (or equivalent)							
*** Abbott Architect**	46	**8.9**	5.7	**10.9**	4.1	**6.0**	4.2
*** Bayer Advia**	31	**9.0**	4.5	**10.9**	8.1	**6.4**	8.0
*** Bayer DCA 2000**	171	**8.8**	3.0	**11.0**	4.5	**6.1**	2.9
*** Beckman Synchron System**	353	**9.0**	4.7	**11.2**	4.4	**6.0**	4.2
*** Bio-Rad D-10**	167	**9.6**	2.7	**11.5**	2.6	**6.3**	2.5
*** Bio-Rad Diastat**	7	**8.9**	-	**10.9**	-	**5.7**	-
*** Bio-Rad Variant A1c**	15	**9.1**	3.2	**11.0**	3.0	**6.2**	2.3
*** Bio-Rad Variant II A1c**	200	**9.6**	2.3	**11.5**	2.1	**6.3**	2.8
*** Bio-Rad Variant II Turbo A1c**	103	**9.4**	2.7	**11.4**	2.6	**6.3**	2.4
*** Dade Behring Dimension**	527	**8.9**	3.1	**10.9**	3.1	**6.3**	3.3
*** Metrika A1cNOW[#]**	19	**8.2**	7.4	**10.2**	6.5	**5.7**	5.7
*** Olympus AU system**	25	**9.4**	3.6	**11.0**	4.1	**6.1**	3.6
*** Primus HPLC (affinity)**	25	**9.0**	4.8	**11.0**	4.7	**6.0**	4.6
*** Roche cobas c501**	20	**9.0**	3.1	**11.0**	3.9	**6.3**	3.4
*** Roche Cobas Integra**	177	**9.2**	4.3	**11.1**	4.0	**6.3**	3.2
*** Roche Cobas Integra Gen.2**	81	**9.0**	2.6	**11.0**	3.2	**6.2**	2.7
*** Roche/Hitachi (Tina Quant II)**	44	**9.1**	3.5	**11.2**	4.5	**6.3**	5.1
*** Tosoh A1c 2.2 Plus**	140	**9.8**	2.5	**12.0**	2.4	**6.5**	3.2
*** Tosoh G7 Auto HPLC**	246	**9.6**	2.0	**11.8**	1.7	**6.4**	2.2
*** Vitros 5,1 FS Chem Syst**	83	**8.9**	4.9	**11.2**	5.3	**6.1**	3.8

		GH2-04		GH2-05		GH2-06	
NGSP Reference Value[t]		**9.2**		**11.1**		**6.2**	
	no. labs	**Median**	%CV	**Median**	%CV	**Median**	%CV
[$]Methods reporting Total GHB							
Primus	16	**12.1**	**5.2**	**15.4**	**5.1**	**7.3**	**5.1**

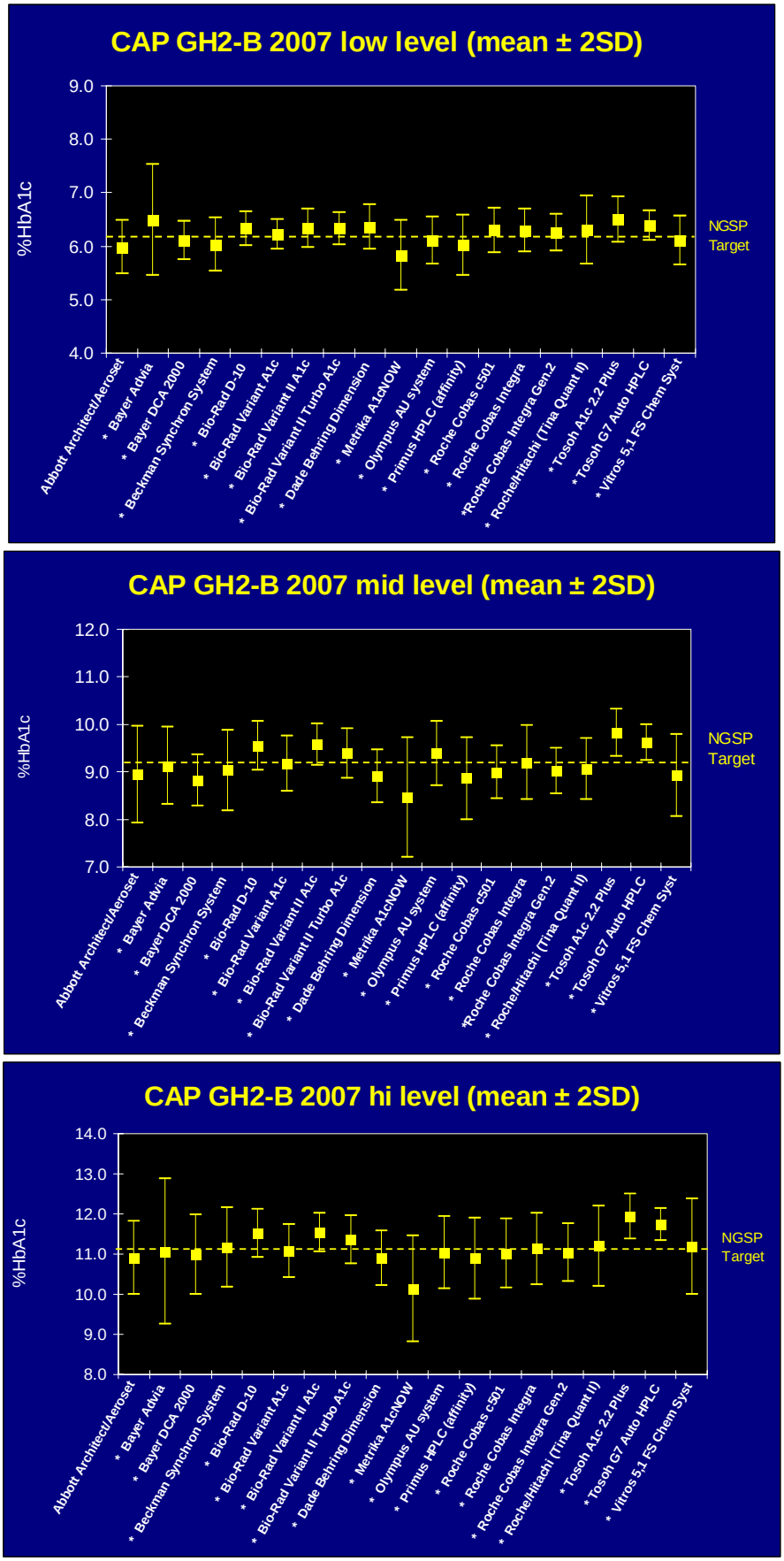
[t] Assigned as the mean value of 6 replicate analyses over two days using 5 NGSP certified secondary reference methods.
[$] Methods reporting Total GHB are not considered NGSP certified even though the same method reporting HbA1c *is* NGSP certified.
[#]EDTA in the CAP sample has been shown by the manufacturer of A1CNow+ to cause artificially low results by this method. Routine samples for this method are from fingerstick and do not include EDTA. The manufacturer recommends the use of heparin anticoagulant instead of EDTA when testing venous samples.

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

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

- **Over 99% of laboratories reported results as HbA1c or equivalent and used a certified method; there were only 16 laboratories (<1%) still reporting total GHB.**
- **For NGSP certified methods, the method-specific medians were all within 0.6, 1.0 and 0.9% 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. The Metrika A1cNow showed an unusually large negative bias (-1.0% and -0.9% HbA1c, respectively) at the mid and high HbA1c levels. EDTA in the CAP sample has been shown by the manufacturer of A1CNow+ to cause artificially low results by this method. Routine samples for this method are from fingerstick and do not include EDTA. The manufacturer recommends the use of heparin anticoagulant instead of EDTA when testing venous samples. The Tosoh 2.2 Plus and G7 methods continue to show high positive biases (0.9 and 0.7% respectively) for the high level HbA1c specimen.**
- **Method-specific, between-laboratory CV's ranged from 1.7% to 8.1%. The Metrika A1c Now showed between-laboratory CVs >5% at all three levels. The Bayer (Siemens) Advia showed a CV >5% at both the low and high levels. 75% of methods had between-lab CVs ≤5.0% at all three HbA1c levels (table above) and the Bio-Rad D-10, Variant II and Variant II Turbo, and Tosoh G7, showed CVs below 3% at all levels.**
- **Bias from the NGSP target and variability (±2SD) are shown in *figure 1* for each method.**
- **This is the second GH2 survey using an accuracy based target (NGSP); peer group means are no longer used for grading the GH2 survey. Currently the acceptable limit is ±15% of the target value; this will change to ±12% in 2008. "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


CAP GH2-B 2007 low level (mean ± 2SD)
%HbA1c
9.0
8.0
7.0
6.0
5.0
4.0
NGSP Target
Abbott Architect/Aeroset
* Bayer Advia
* Bayer DCA 2000
* Beckman Synchron System
* Bio-Rad D-10
* Bio-Rad Variant A1c
* Bio-Rad Variant II A1c
* Bio-Rad Variant II Turbo A1c
* Dade Behring Dimension
* Metrika A1cNOW
* Olympus AU system
* Primus HPLC (affinity)
* Roche Cobas c501
* Roche Cobas Integra
*Roche Cobas Integra Gen.2
* Roche/Hitachi (Tina Quant II)
* Tosoh A1c 2.2 Plus
* Tosoh G7 Auto HPLC
* Vitros 5,1 FS Chem Syst
CAP GH2-B 2007 mid level (mean ± 2SD)
%HbA1c
12.0
11.0
10.0
9.0
8.0
7.0
NGSP Target
Abbott Architect/Aeroset
* Bayer Advia
* Bayer DCA 2000
* Beckman Synchron System
* Bio-Rad D-10
* Bio-Rad Variant A1c
* Bio-Rad Variant II A1c
* Bio-Rad Variant II Turbo A1c
* Dade Behring Dimension
* Metrika A1cNOW
* Olympus AU system
* Primus HPLC (affinity)
* Roche Cobas c501
* Roche Cobas Integra
*Roche Cobas Integra Gen.2
* Roche/Hitachi (Tina Quant II)
* Tosoh A1c 2.2 Plus
* Tosoh G7 Auto HPLC
* Vitros 5,1 FS Chem Syst
CAP GH2-B 2007 hi level (mean ± 2SD)
%HbA1c
14.0
13.0
12.0
11.0
10.0
9.0
8.0
NGSP Target
Abbott Architect/Aeroset
* Bayer Advia
* Bayer DCA 2000
* Beckman Synchron System
* Bio-Rad D-10
* Bio-Rad Variant A1c
* Bio-Rad Variant II A1c
* Bio-Rad Variant II Turbo A1c
* Dade Behring Dimension
* Metrika A1cNOW
* Olympus AU system
* Primus HPLC (affinity)
* Roche Cobas c501
* Roche Cobas Integra
* Roche Cobas Integra Gen.2
* Roche/Hitachi (Tina Quant II)
* Tosoh A1c 2.2 Plus
* Tosoh G7 Auto HPLC
* Vitros 5,1 FS Chem Syst

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.