College of American Pathologists (CAP) Survey Data:

(updated 12/08)

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 first survey of 2008 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 seven NGSP certified secondary reference methods.

2008 GH2-B (fresh pooled samples)

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

		GH2-04		GH2-05		GH2-06	
NGSP Reference Value[t]		**11.9**		**6.8**		**5.0**	
	no. labs	**Median**	%CV	**Median**	%CV	**Median**	%CV
Methods reporting HbA1c (or equivalent)							
*** Abbott Architect/Aeroset**	47	**11.7**	4.8	**6.9**	4.3	**5.0**	5.3
*** Beckman Synchron System**	389	**11.8**	4.5	**6.5**	4	**5.0**	4.7
*** Bio-Rad D-10**	200	**12.1**	2.8	**6.9**	2.9	**5.0**	3.9
*** Bio-Rad Variant A1c**	13	**12.0**	3	**6.8**	1.6	**4.9**	2.9
*** Bio-Rad Variant II A1c**	167	**12.4**	2.6	**7.0**	3	**5.0**	4
*** Bio-Rad Variant II Turbo A1c**	132	**12.0**	2.5	**7.0**	2.7	**5.2**	3.2
*** Dade Behring Dimension**	578	**12.3**	4.6	**6.9**	3.7	**5.4**	3.5
*** Dade Behring Dimension Vista**	13	**11.4**	2.4	**7.2**	4.6	**5.0**	4.7
*** Metrika A1cNOW[#]**	20	**10.4**	6.9	**6.1**	7.7	**4.8**	7
*** Olympus AU system**	25	**11.9**	6.3	**6.7**	4.9	**4.9**	4
*** Primus HPLC (affinity)**	32	**12.0**	2.2	**6.8**	3.2	**5.1**	2.7
*** Roche Cobas c501**	73	**11.4**	3.6	**6.7**	3.2	**5.3**	2.6
*** Roche Cobas Integra**	121	**11.7**	3.4	**6.8**	3.3	**5.2**	3
*** Roche Cobas Integra Gen.2**	101	**11.6**	3.4	**6.8**	3.4	**5.2**	2.8
*** Roche/Hitachi (Tina Quant II)**	41	**11.7**	3.1	**6.8**	4.6	**5.2**	4.5
*** Siemens Advia 1650/2400**	42	**12.0**	5.1	**7.0**	3.6	**5.3**	4.2
*** Siemens DCA 2000**	178	**12.0**	4.9	**6.8**	2.6	**5.1**	2.6
*** Tosoh A1c 2.2 Plus**	113	**12.3**	3.3	**7.2**	2.8	**5.3**	3.1
*** Tosoh G7 Auto HPLC**	294	**12.0**	2.1	**7.0**	1.8	**5.2**	1.9
*** Vitros 5,1 FS Chem Syst**	117	**11.5**	4.5	**6.6**	2.5	**5.2**	3.6

		GH2-04		GH2-05		GH2-06	
NGSP Reference Value[t]		**11.9**		**6.8**		**5.0**	
	no. labs	**Median**	%CV	**Median**	%CV	**Median**	%CV
[$]Methods reporting Total GHB							
Primus	20	**17.5**	**2.1**	**8.7**	**1.7**	**5.7**	**4.2**

[t] Assigned as the mean value of 6 replicate analyses over two days using 7 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

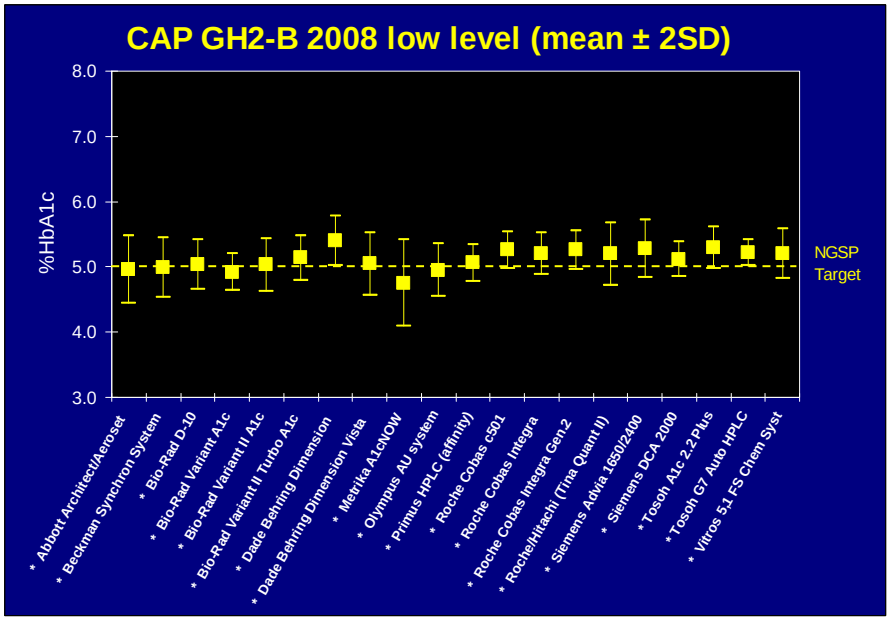
In 2008, based on data from the GH2-B survey:

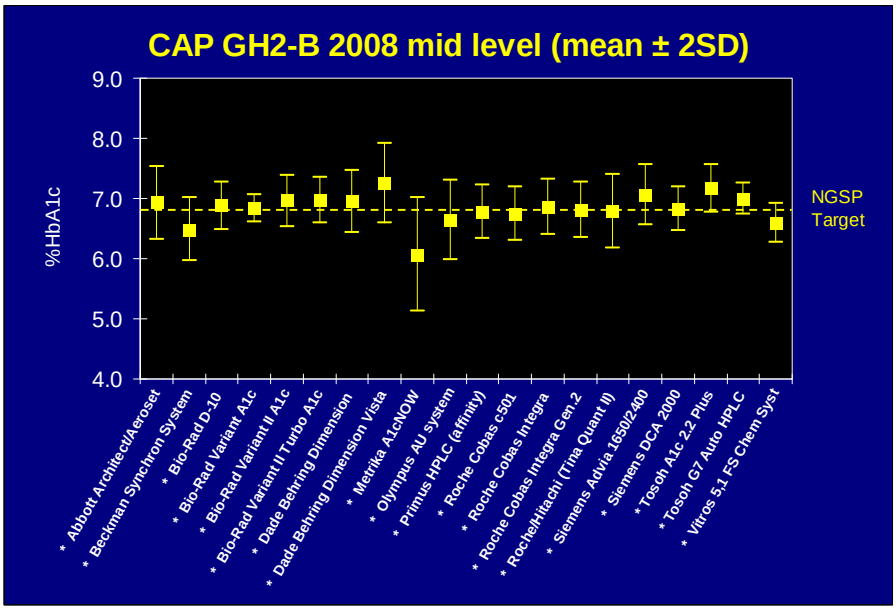
- **Over 99% of laboratories reported results as HbA1c or equivalent and used a certified method; there were only 20 laboratories (<1%) still reporting total GHB.**
- **Bias from the NGSP target and variability (±2SD) are shown in *figure 1* for each method.**
- **For NGSP certified methods, other than the Metrika A1cNow[#] (see footnote above), the method-specific medians were all within 0.4, 0.4 and 0.5% HbA1c of NGSP targets at the low, mid and high HbA1c levels, respectively (table above). Bias for the Tosoh 2.2 Plus and G7 methods at the high HbA1c level is considerably lower than in previous surveys.**
- **Method-specific, between-laboratory CV's ranged from 1.6% to 7.7%. The Metrika A1c Now is the only method that showed between-laboratory CVs >5% at all three levels. Three other methods showed CVs >5% for only 1 level. More than 95% of laboratories were using methods that had between-lab CVs ≤5.0% at all three HbA1c levels**
- **This is the fourth GH2 survey using an accuracy based target (NGSP); peer group means are no longer used for grading the GH2 survey. The acceptable limit for this survey is ±12% of the target value; the acceptable limit for grading will be reduced to ±10% in the next survey. The overall pass rate ranged from 95.5 to 98.6%, depending on the HbA1c level. For individual methods, the lowest pass rate was 85% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-B 2008). Methods with low bias and low CVs will have the highest pass rates and conversely, methods with either high bias and/or high CVs or both will have the lowest pass rates.**
- ***Figure 2 and 3* examines the bias (2) and CV (3) trends for the 2006 through 2008B surveys for the 11 most used methods (methods with >100 users on the 2008B survey). Note that the variability is somewhat dependent on the exact HbA1c level; the target %HbA1c for the mid level was lowest for the 2008B survey (6.8% HbA1c) and highest for the 2007B survey (9.2%). There is a decrease in the bias for this most recent survey for all three levels but this may in large part be due to the fact that the HbA1c levels are lower for each sample compared to those in the 2008A survey.**

NOTE: The NGSP evaluates bias 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.

Figure 1


CAP GH2-B 2008 low level (mean ± 2SD)
%HbA1c
8.0
7.0
6.0
5.0
4.0
3.0
NGSP Target
* Abbott Architect/Aeroset
* 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
* Dade Behring Dimension Vista
* Metrika A1cNOW
* Olympus AU system
* Primus HPLC (affinity)
* Roche Cobas c501
* Roche Cobas Integra
* Roche Cobas Integra Gen.2
* Roche/Hitachi (Tina Quant II)
* Siemens Advia 1650/2400
* Siemens DCA 2000
* Tosoh A1c 2.2 Plus
* Tosoh G7 Auto HPLC
* Vitros 5,1 FS Chem Syst


CAP GH2-B 2008 mid level (mean ± 2SD)
%HbA1c
9.0
8.0
7.0
6.0
5.0
4.0
NGSP Target
* Abbott Architect/Aeroset
* 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
* Dade Behring Dimension Vista
* Metrika A1cNOW
* Olympus AU system
* Primus HPLC (affinity)
* Roche Cobas c501
* Roche Cobas Integra
* Roche Cobas Integra Gen.2
* Roche/Hitachi (Tina Quant II)
* Siemens Advia 1650/2400
* Siemens DCA 2000
* Tosoh A1c 2.2 Plus
* Tosoh G7 Auto HPLC
* Vitros 5,1 FS Chem Syst

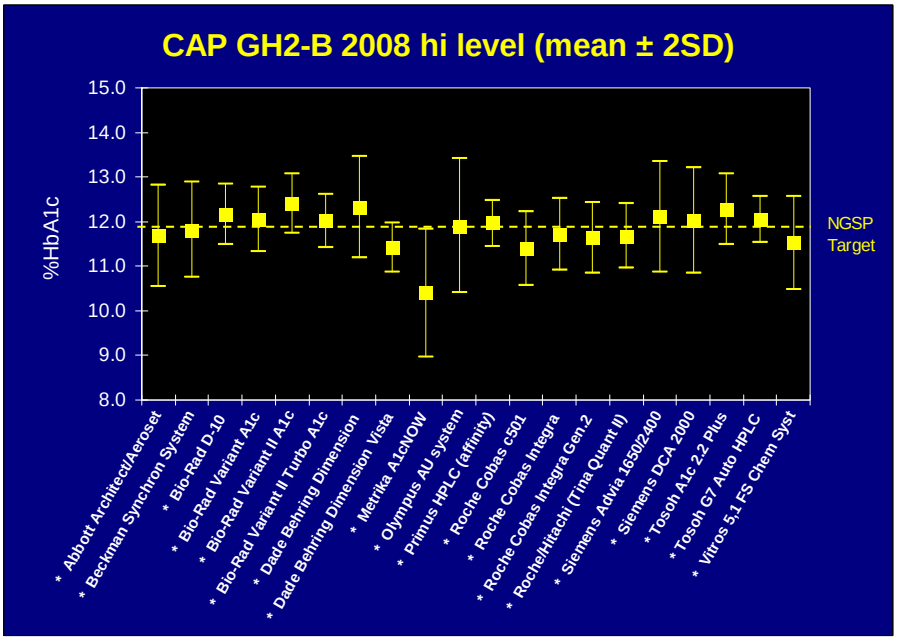
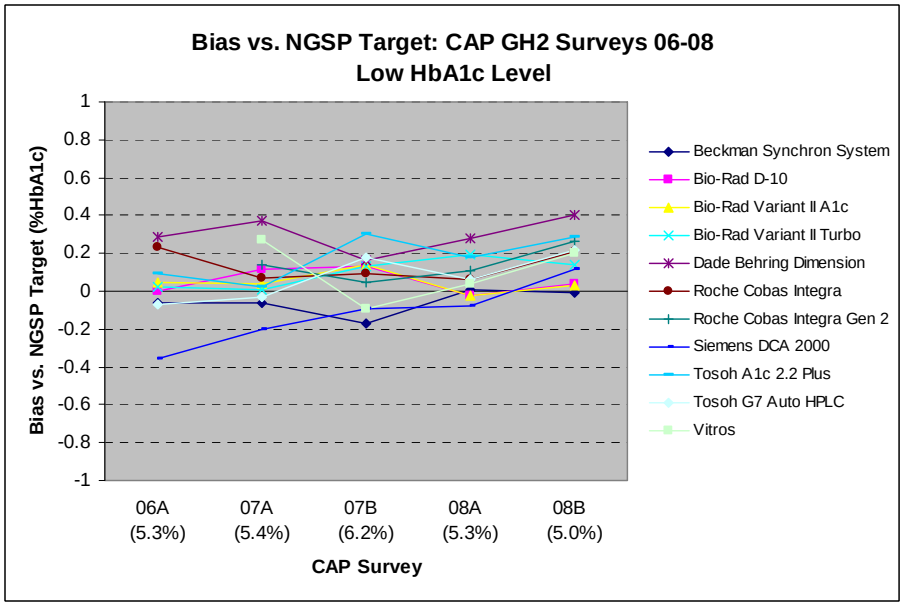
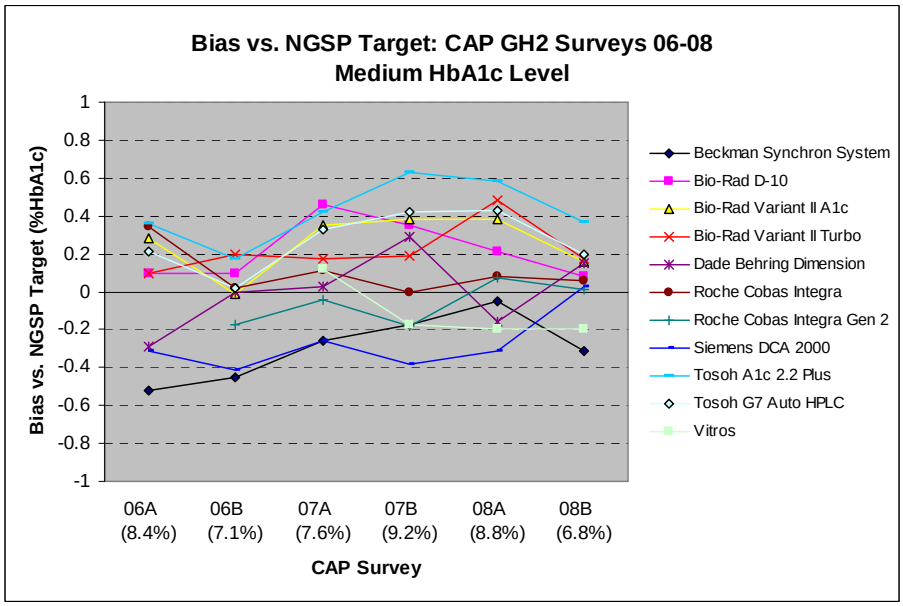

CAP GH2-B 2008 hi level (mean ± 2SD)
%HbA1c
15.0
14.0
13.0
12.0
11.0
10.0
9.0
8.0
NGSP Target
* Abbott Architect/Aeroset
* Beckman Synchron System
* Bio-Rad D-10
* Bio-Rad Variant A1c
* Bio-Rad Variant II A1c
* Bio-Rad Variant II Turbo A1c
* Dade Behring Dimension
* Dade Behring Dimension Vista
* Metrika A1cNOW
* Olympus AU system
* Primus HPLC (affinity)
* Roche Cobas c501
* Roche Cobas Integra
* Roche Cobas Integra Gen.2
* Roche/Hitachi (Tina Quant II)
* Siemens Advia 1650/2400
* Siemens DCA 2000
* Tosoh A1c 2.2 Plus
* Tosoh G7 Auto HPLC
* Vitros 5,1 FS Chem Syst

Figure 2


Bias vs. NGSP Target: CAP GH2 Surveys 06-08
Low HbA1c Level
Bias vs. NGSP Target (%HbA1c)
1
0.8
0.6
0.4
0.2
0
-0.2
-0.4
-0.6
-0.8
-1
06A (5.3%)
07A (5.4%)
07B (6.2%)
08A (5.3%)
08B (5.0%)
CAP Survey
Beckman Synchron System
Bio-Rad D-10
Bio-Rad Variant II A1c
Bio-Rad Variant II Turbo
Dade Behring Dimension
Roche Cobas Integra
Roche Cobas Integra Gen 2
Siemens DCA 2000
Tosoh A1c 2.2 Plus
Tosoh G7 Auto HPLC
Vitros


Bias vs. NGSP Target: CAP GH2 Surveys 06-08
Medium HbA1c Level
Bias vs. NGSP Target (%HbA1c)
1
0.8
0.6
0.4
0.2
0
-0.2
-0.4
-0.6
-0.8
-1
06A (8.4%)
06B (7.1%)
07A (7.6%)
07B (9.2%)
08A (8.8%)
08B (6.8%)
CAP Survey
Beckman Synchron System
Bio-Rad D-10
Bio-Rad Variant II A1c
Bio-Rad Variant II Turbo
Dade Behring Dimension
Roche Cobas Integra
Roche Cobas Integra Gen 2
Siemens DCA 2000
Tosoh A1c 2.2 Plus
Tosoh G7 Auto HPLC
Vitros

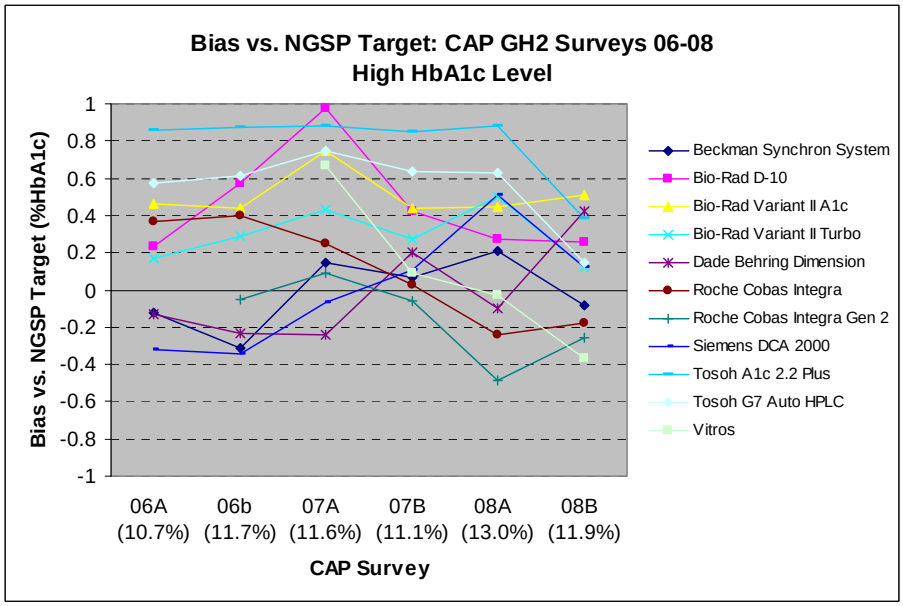
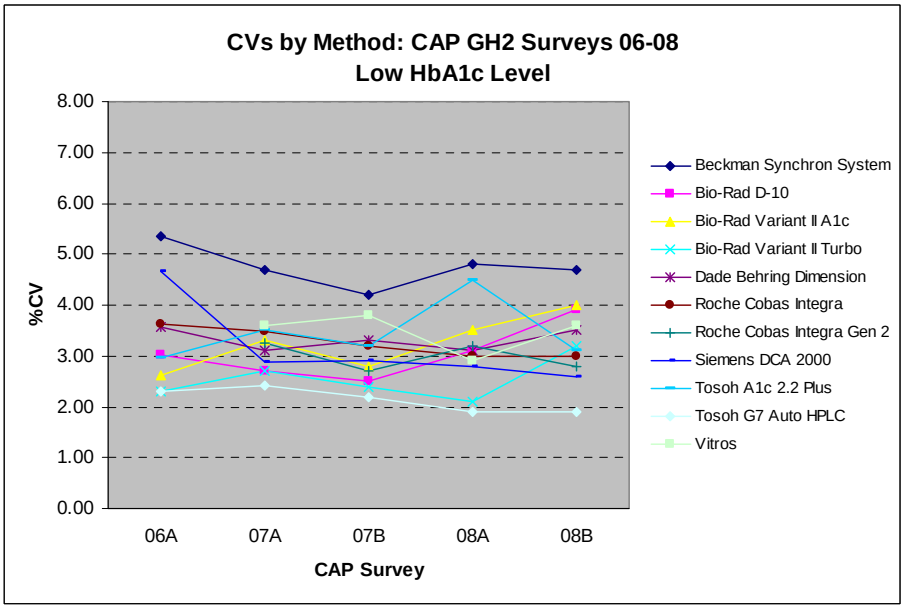
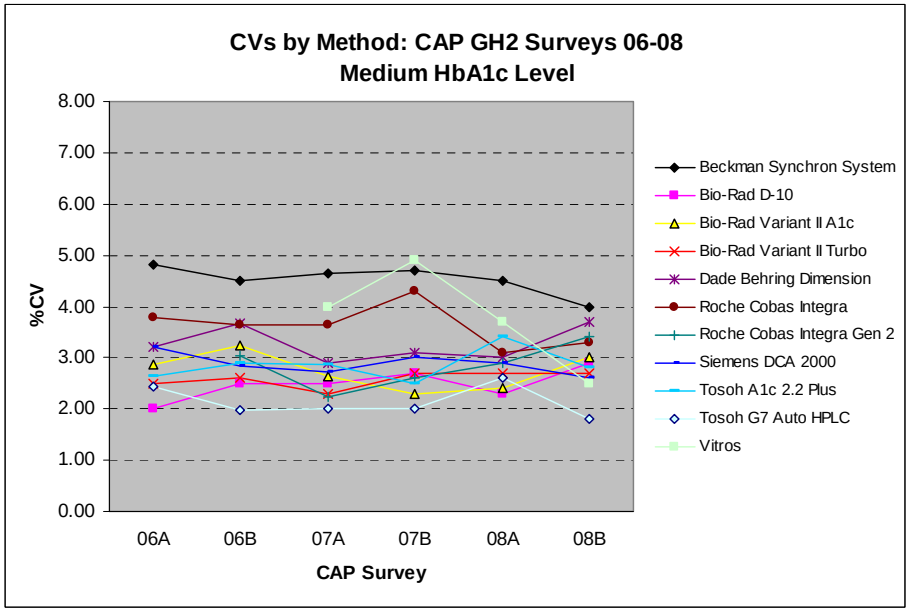
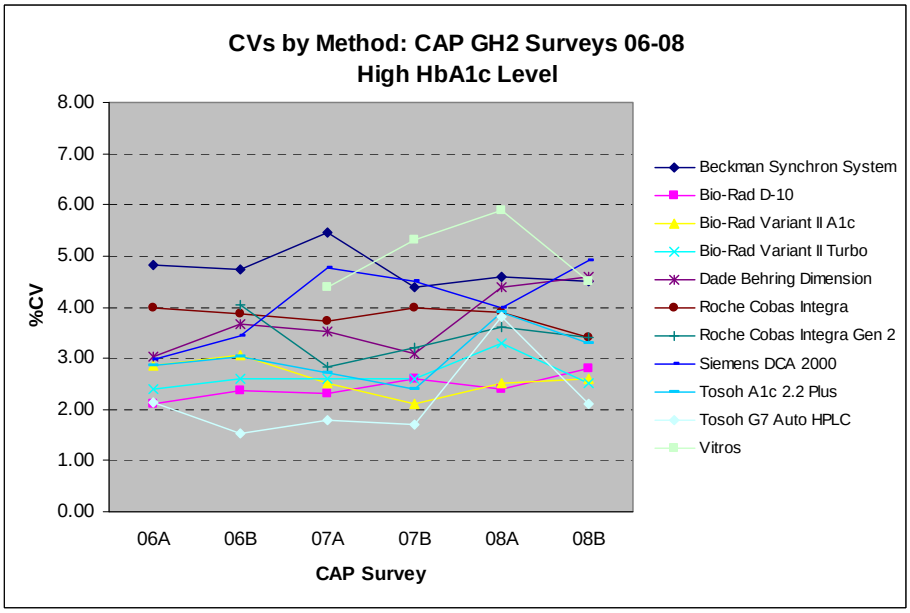

Bias vs. NGSP Target: CAP GH2 Surveys 06-08
High HbA1c Level
Bias vs. NGSP Target (%HbA1c)
1
0.8
0.6
0.4
0.2
0
-0.2
-0.4
-0.6
-0.8
-1
06A (10.7%)
06b (11.7%)
07A (11.6%)
07B (11.1%)
08A (13.0%)
08B (11.9%)
CAP Survey
Beckman Synchron System
Bio-Rad D-10
Bio-Rad Variant II A1c
Bio-Rad Variant II Turbo
Dade Behring Dimension
Roche Cobas Integra
Roche Cobas Integra Gen 2
Siemens DCA 2000
Tosoh A1c 2.2 Plus
Tosoh G7 Auto HPLC
Vitros

Figure 3


CVs by Method: CAP GH2 Surveys 06-08
Low HbA1c Level
%CV
8.00
7.00
6.00
5.00
4.00
3.00
2.00
1.00
0.00
06A
07A
07B
08A
08B
CAP Survey
Beckman Synchron System
Bio-Rad D-10
Bio-Rad Variant II A1c
Bio-Rad Variant II Turbo
Dade Behring Dimension
Roche Cobas Integra
Roche Cobas Integra Gen 2
Siemens DCA 2000
Tosoh A1c 2.2 Plus
Tosoh G7 Auto HPLC
Vitros


CVs by Method: CAP GH2 Surveys 06-08
Medium HbA1c Level
%CV
8.00
7.00
6.00
5.00
4.00
3.00
2.00
1.00
0.00
06A
06B
07A
07B
08A
08B
CAP Survey
Beckman Synchron System
Bio-Rad D-10
Bio-Rad Variant II A1c
Bio-Rad Variant II Turbo
Dade Behring Dimension
Roche Cobas Integra
Roche Cobas Integra Gen 2
Siemens DCA 2000
Tosoh A1c 2.2 Plus
Tosoh G7 Auto HPLC
Vitros


CVs by Method: CAP GH2 Surveys 06-08
High HbA1c Level
%CV
8.00
7.00
6.00
5.00
4.00
3.00
2.00
1.00
0.00
06A
06B
07A
07B
08A
08B
CAP Survey
Beckman Synchron System
Bio-Rad D-10
Bio-Rad Variant II A1c
Bio-Rad Variant II Turbo
Dade Behring Dimension
Roche Cobas Integra
Roche Cobas Integra Gen 2
Siemens DCA 2000
Tosoh A1c 2.2 Plus
Tosoh G7 Auto HPLC
Vitros