College of American Pathologists (CAP) GH2 Survey Data:

(updated 5/09)

The American Diabetes Association (ADA) recommends that laboratories use only HbA1c assay methods that have been NGSP certified and report results as "%HbA1c" or "%HbA1c equivalents". The ADA also recommends that all laboratories performing HbA1c 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 2009 are summarized below. The NGSP target or reference values are based on replicate analyses using seven NGSP certified secondary reference methods.

2009 GH2-A (fresh pooled samples)

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

		GH2-01		GH2-02		GH2-03	
NGSP Reference Value[t]		**5.10**		**8.40**		**6.00**	
	no. labs	**Median**	%CV	**Median**	%CV	**Median**	%CV
Methods reporting HbA1c (or equivalent)							
*** Abbott Architect/Aeroset**	47	**4.9**	5.8	**8.2**	4.3	**5.8**	8.0
*** Beckman Synchron CX System**	32	**5.0**	3.4	**7.9**	4.4	**5.8**	5.3
*** Beckman Synchron LX System**	85	**5.0**	4.9	**8.2**	3.7	**5.8**	3.8
*** Beckman Unicel DxC Synchron**	210	**5.0**	3.7	**8.1**	3.5	**5.8**	3.5
*** Bio-Rad D-10**	191	**5.1**	3.2	**8.5**	2.3	**6.1**	3.0
*** Bio-Rad Variant II A1c**	146	**5.1**	3.6	**8.7**	2.8	**6.2**	2.8
*** Bio-Rad Variant II Turbo A1c**	130	**5.1**	2.8	**8.5**	2.5	**6.0**	2.6
*** Metrika A1cNOW[#]**	17	**4.6**	5.0	**7.2**	6.0	**5.3**	5.2
*** Olympus AU 400/400e**	15	**4.8**	5.3	**8.1**	7.3	**5.6**	5.7
*** Primus HPLC (affinity)**	12	**5.1**	2.8	**8.3**	2.8	**5.9**	2.3
*** Roche Cobas c501**	108	**5.3**	3.3	**8.2**	3.6	**6.0**	3.4
*** Roche Cobas Integra 400 Gen.2**	26	**5.2**	4.1	**8.5**	2.4	**6.1**	3.6
*** Roche Cobas Integra 400 (non TQ)**	20	**5.3**	2.9	**8.7**	3.3	**6.2**	3.3
*** Roche Cobas Integra 800 Gen.2**	116	**5.3**	3.9	**8.5**	3.6	**6.1**	3.3
*** Roche Cobas Integra 800 (non TQ)**	11	**5.2**	4.9	**8.5**	3.1	**6.1**	3.4
*** Roche/Hitachi Modular P**	20	**5.2**	3.2	**8.3**	3.2	**6.0**	4.7
*** Siemens Advia 1650**	16	**5.1**	4.1	**8.3**	3.0	**6.1**	2.7
*** Siemens Advia 1800**	14	**5.1**	5.4	**8.4**	4.1	**6.1**	5.1
*** Siemens DCA 2000/200+**	134	**5.1**	2.9	**8.4**	3.3	**6.0**	3.3
*** Siemens DCA Vantage**	59	**5.1**	2.3	**8.4**	2.6	**6.0**	2.9
*** Siemens Dimension ExL**	12	**5.4**	3.7	**8.4**	3.6	**6.2**	3.1
*** Siemens Dimension RxL**	346	**5.4**	3.7	**8.4**	4.1	**6.1**	3.9
*** Siemens Dimension Vista**	22	**4.9**	4.0	**8.6**	2.3	**6.1**	5.6

		GH2-01		GH2-02		GH2-03	
NGSP Reference Value[t]		**5.10**		**8.40**		**6.00**	
	no. labs	**Median**	%CV	**Median**	%CV	**Median**	%CV
*** Siemens Dimension Xpand**	139	**5.3**	3.8	**8.3**	4.1	**6.0**	3.9
*** Tosoh A1c 2.2 Plus**	91	**5.3**	3.5	**8.7**	2.6	**6.3**	2.8
*** Tosoh G7 Auto HPLC**	240	**5.2**	1.7	**8.6**	1.4	**6.2**	1.5
*** Tosoh G8 Auto HPLC**	41	**5.2**	1.8	**8.5**	1.2	**6.2**	1.3
*** Vitros 5,1 FS Chem Syst**	111	**5.1**	3.4	**8.3**	3.8	**5.9**	3.9

[t] Assigned as the mean of 3 replicate analyses per day for two days per method using 7 NGSP certified secondary reference methods.

[#] 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

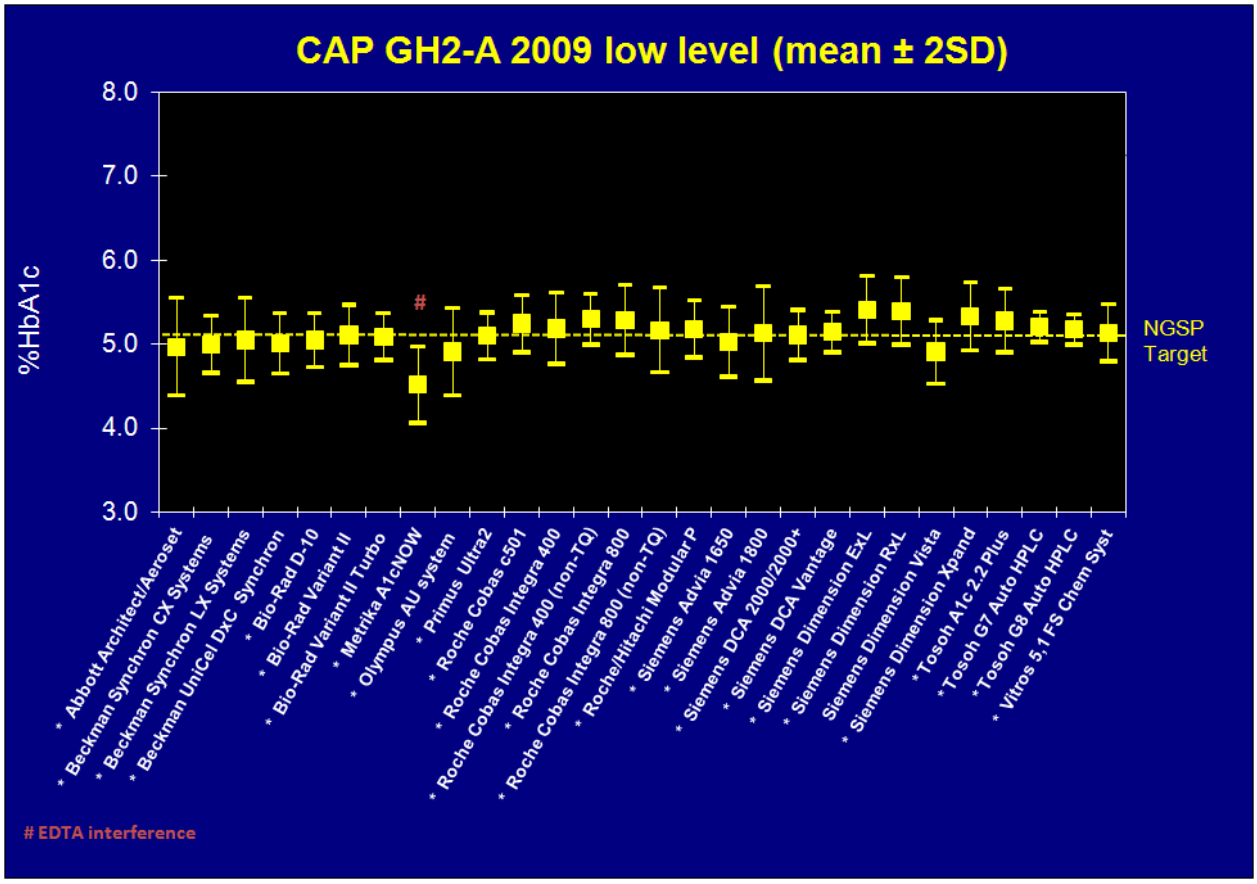
In 2009, based on data from the GH2-A survey:

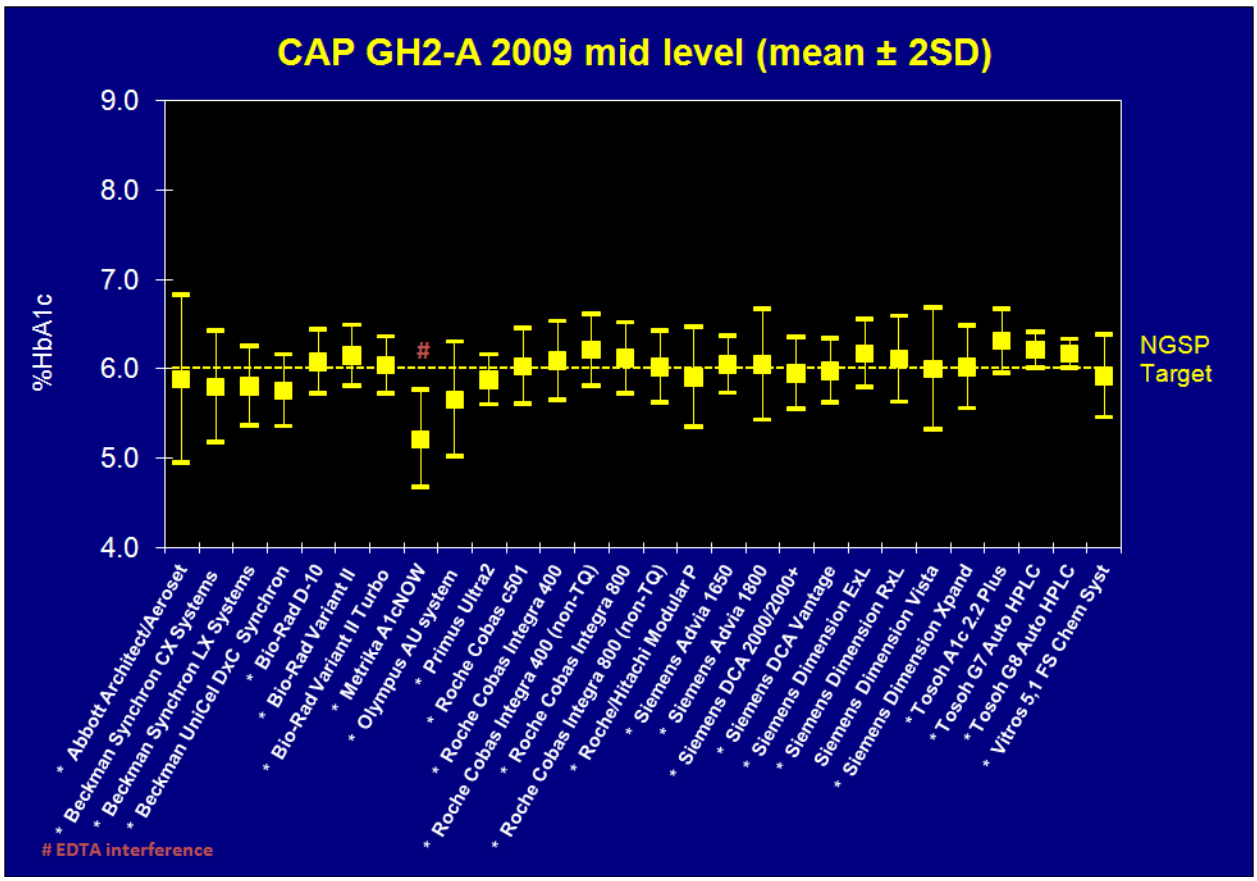
- **Only HbA1c results are included in this CAP survey report. Laboratories reporting total GHB are not included.**
- **Some methods are now divided into smaller groups, e.g. the three Beckman instruments are listed separately.**
- **The HbA1c levels for this survey are quite a bit lower than in previous surveys; the high level is only 8.4% (assigned value).**
- **Bias from the NGSP target and variability (±2SD) are shown in *figure 1* for each method. Other than the Metrika A1cNow[#] (see footnote above), the method-specific medians were all within 0.3, 0.4 and 0.5% HbA1c of NGSP targets at the low, mid and high HbA1c levels, respectively (table above). Many methods showed less than 0.3% HbA1c bias for all levels.**
- **Method-specific, between-laboratory CV's ranged from 1.2% to 8.0%. Only one method (Olympus AU 400) showed between-laboratory CVs >5% at all three levels. Three methods showed CVs >5% for 2 levels. However, approximately 95% of laboratories were using methods that had between-lab CVs ≤5.0% at all three HbA1c levels.**
- **This is the fifth GH2 survey using an accuracy based target (NGSP); peer group means are no longer used for grading the GH2 survey (except for the Metrika method due to its EDTA interference). The acceptable limit for this survey is ±10% of the target value; the acceptable limit for grading will be reduced to ±8% in 2010 and ±6% in 2011. The overall pass rate for this survey ranged from 95.2 to 97.1%, depending upon the HbA1c level. For individual methods, the lowest pass rate was 80% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-A 2009). Methods with small bias and low CVs will have the highest pass rates and, conversely, methods with large bias and/or high CVs will have the lowest pass rates.**
- ***Figures 2 and 3* examine the bias (fig 1) and CV (fig 2) trends for the 2006 through 2009A surveys for the 12 most used methods. The survey samples are now grouped by HbA1c level: Low Level: 5-6.5% HbA1c, Medium (1) Level: 6.6-8.5% HbA1c, Medium (2) Level: 8.6-10% HbA1c, and High Level: >10% HbA1c. Only the Low and Medium (1) levels are shown since this is the most relevant range for diabetes treatment and diagnosis. There appears to be a decrease in the overall bias and CV over**

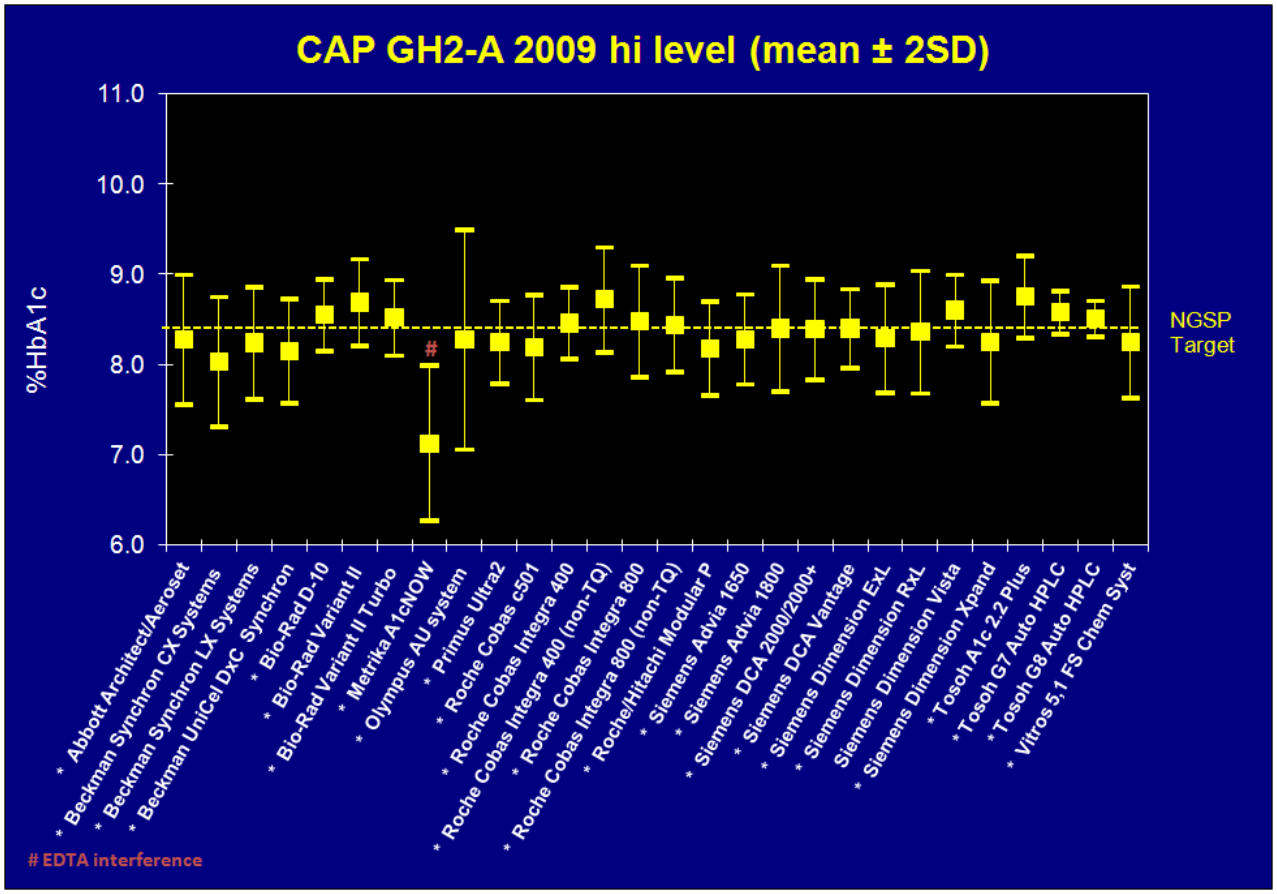
time , although one method (Abbott Architect) has shown a significant increase in CV at the low HbA1c level over the last two surveys.

NOTE: The NGSP evaluates agreement at 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-A 2009 low level (mean ± 2SD)
%HbA1c
8.0
7.0
6.0
5.0
4.0
3.0
#
NGSP Target
* Abbott Architect/Aeroset
* Beckman Synchron CX Systems
* Beckman Synchron LX Systems
* Beckman UniCel DxC Synchron
* Bio-Rad D-10
* Bio-Rad Variant II
* Bio-Rad Variant II Turbo
* Metrika A1cNOW
* Olympus AU system
* Primus Ultra2
* Roche Cobas c501
* Roche Cobas Integra 400
* Roche Cobas Integra 400 (non-TQ)
* Roche Cobas Integra 800
* Roche Cobas Integra 800 (non-TQ)
* Roche/Hitachi Modular P
* Siemens Advia 1650
* Siemens Advia 1800
* Siemens DCA 2000/2000+
* Siemens DCA Vantage
* Siemens Dimension ExL
* Siemens Dimension RxL
* Siemens Dimension Vista
* Siemens Dimension Xpand
* Tosoh A1c 2.2 Plus
* Tosoh G7 Auto HPLC
* Tosoh G8 Auto HPLC
* Vitros 5,1 FS Chem Syst
# EDTA interference


CAP GH2-A 2009 mid level (mean ± 2SD)
%HbA1c
9.0
8.0
7.0
6.0
5.0
4.0
#
NGSP Target
* Abbott Architect/Aeroset
* Beckman Synchron CX Systems
* Beckman Synchron LX Systems
* Beckman UniCel DxC Synchron
* Bio-Rad D-10
* Bio-Rad Variant II
* Bio-Rad Variant II Turbo
* Metrika A1cNOW
* Olympus AU system
* Primus Ultra2
* Roche Cobas c501
* Roche Cobas Integra 400
* Roche Cobas Integra 400 (non-TQ)
* Roche Cobas Integra 800
* Roche Cobas Integra 800 (non-TQ)
* Roche/Hitachi Modular P
* Siemens Advia 1650
* Siemens Advia 1800
* Siemens DCA 2000/2000+
* Siemens DCA Vantage
* Siemens Dimension ExL
* Siemens Dimension RxL
* Siemens Dimension Vista
* Siemens Dimension Xpand
* Tosoh A1c 2.2 Plus
* Tosoh G7 Auto HPLC
* Tosoh G8 Auto HPLC
* Vitros 5,1 FS Chem Syst
# EDTA interference


CAP GH2-A 2009 hi level (mean ± 2SD)
%HbA1c
11.0
10.0
9.0
8.0
7.0
6.0
NGSP Target
#
* Abbott Architect/Aeroset
* Beckman Synchron CX Systems
* Beckman Synchron LX Systems
* Beckman UniCel DxC Synchron
* Bio-Rad D-10
* Bio-Rad Variant II
* Bio-Rad Variant II Turbo
* Metrika A1cNOW
* Olympus AU system
* Primus Ultra2
* Roche Cobas c501
* Roche Cobas Integra 400
* Roche Cobas Integra 400 (non-TQ)
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* Siemens Advia 1650
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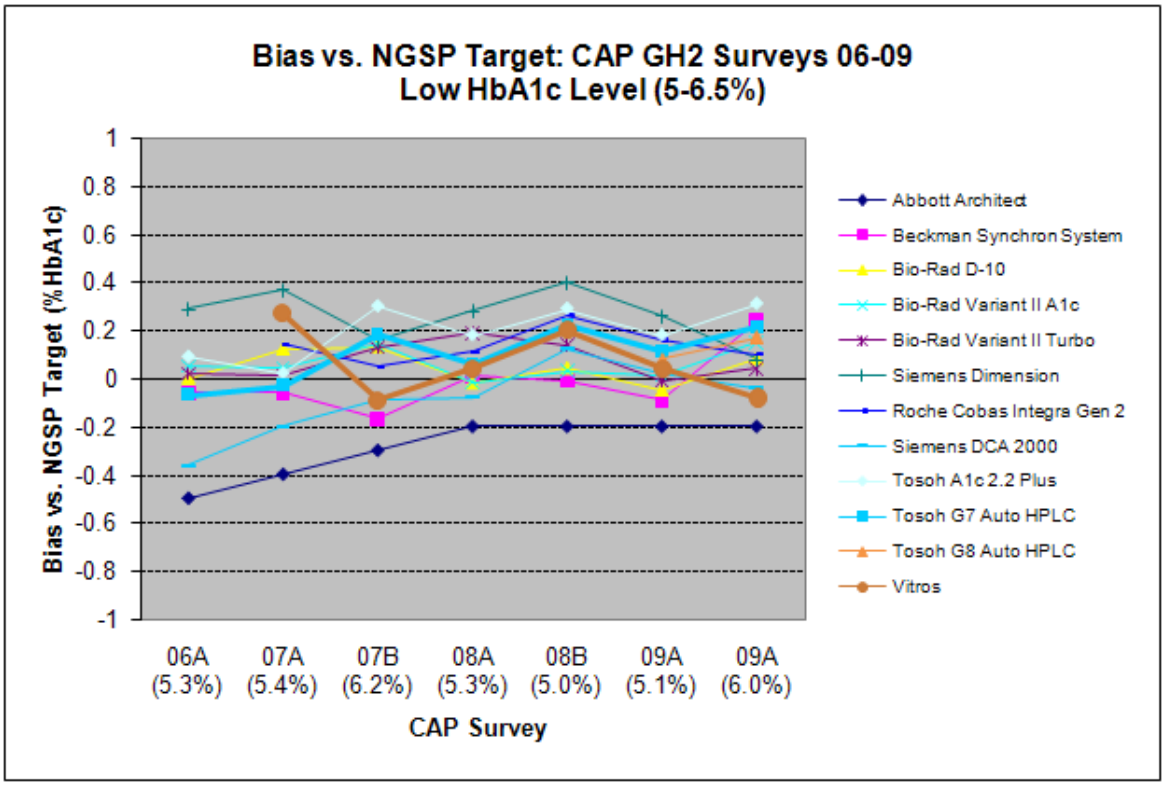
* Siemens Dimension RxL
* Siemens Dimension Vista
* Siemens Dimension Xpand
* Tosoh A1c 2.2 Plus
* Tosoh G7 Auto HPLC
* Tosoh G8 Auto HPLC
* Vitros 5,1 FS Chem Syst
# EDTA interference

Figure 2: Bias Trend by Method



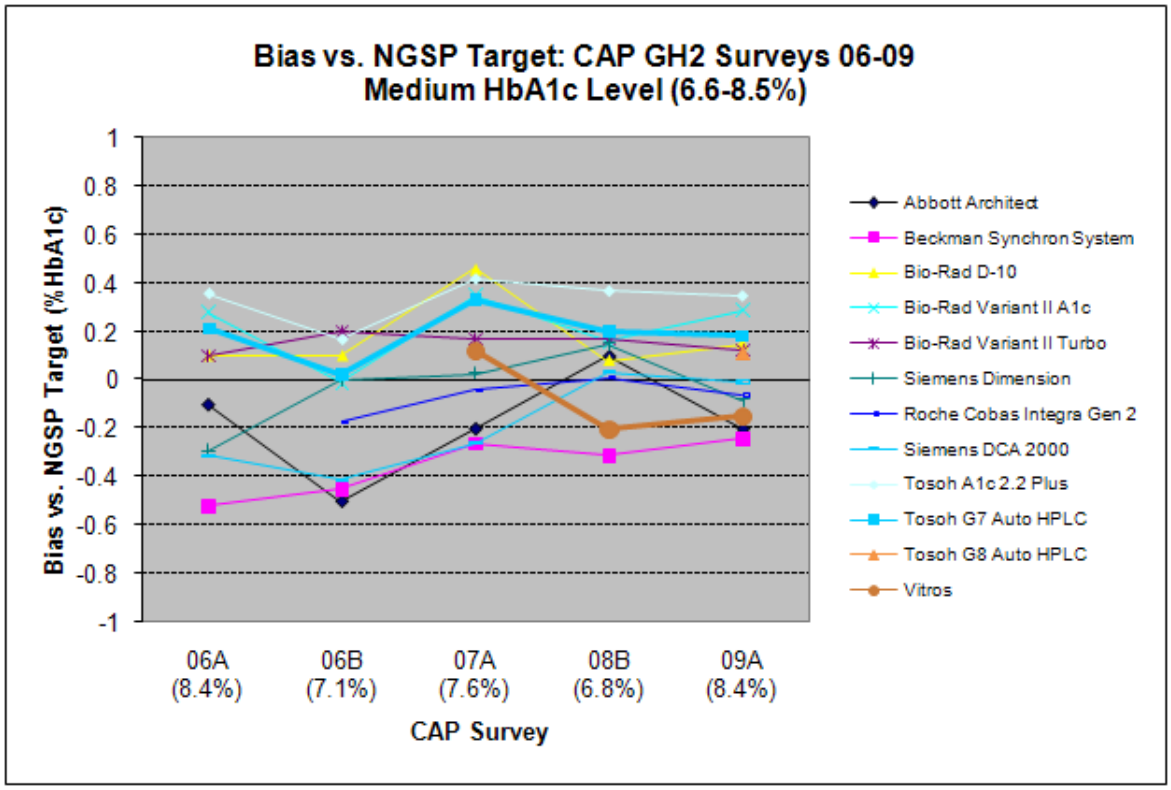


Figure 3: %CV Trend by Method