

# College of American Pathologists (CAP) GH2 Survey Data:

(updated 4/11)

The American Diabetes Association (ADA) recommends that laboratories use only HbA1c assay methods that have been NGSP certified and report results as “%HbA1c”. 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 2011 are summarized below. The NGSP target or reference values are based on replicate analyses using seven NGSP certified secondary reference methods.

## 2011 GH2-A (fresh pooled samples)

		GH2-01			GH2-02			GH2-03		
NGSP Reference Value (%HbA1c) <sup>t</sup>		8.5			5.4			6.4		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
* Abbott Architect	59	8.73	<b>0.23</b>	3.5	<b>5.38</b>	<b>-0.02</b>	3.3	6.56	<b>0.16</b>	3.0
* Axis-Shield Afinion	18	8.54	<b>0.04</b>	2.2	<b>5.6</b>	<b>0.2</b>	2.7	6.56	<b>0.16</b>	3.3
* Bayer (Metrika) A1cNOW <sup>#</sup>	19	7.96	<b>-0.54</b>	5.5	<b>5.14</b>	<b>-0.26</b>	4.9	6.02	<b>-0.38</b>	5.2
* Beckman AU system	19	8.41	<b>-0.09</b>	3.4	<b>5.43</b>	<b>0.03</b>	3.2	6.43	<b>0.03</b>	3.1
* Beckman Synchron CX Systems	12	8.43	<b>-0.07</b>	3.9	<b>5.42</b>	<b>0.02</b>	7.2	6.48	<b>0.08</b>	7.2
* Beckman Synchron LX Systems	39	8.55	<b>0.05</b>	4.3	<b>5.52</b>	<b>0.12</b>	5.1	6.41	<b>0.01</b>	4.5
* Beckman UniCel Dx C Synchron	263	8.52	<b>0.02</b>	3.1	<b>5.45</b>	<b>0.05</b>	3.9	6.38	<b>-0.02</b>	3.4
* Bio-Rad D-10	199	8.72	<b>0.22</b>	2.4	<b>5.41</b>	<b>0.01</b>	2.9	6.44	<b>0.04</b>	2.8
* Bio-Rad Variant II	107	8.65	<b>0.15</b>	2.2	<b>5.47</b>	<b>0.07</b>	2.8	6.48	<b>0.08</b>	2.2
* Bio-Rad Variant II Turbo	148	8.59	<b>0.09</b>	2.4	<b>5.42</b>	<b>0.02</b>	2.7	6.45	<b>0.05</b>	2.4
* Bio-Rad Variant II Turbo 2.0	30	8.70	<b>0.20</b>	2.1	<b>5.57</b>	<b>0.17</b>	2.4	6.59	<b>0.19</b>	2.2
* Roche Cobas c500/700	171	8.47	<b>-0.03</b>	3.0	<b>5.58</b>	<b>0.18</b>	3.3	6.52	<b>0.12</b>	3.0
* Roche Cobas Integra 400	52	8.68	<b>0.18</b>	3.8	<b>5.58</b>	<b>0.18</b>	3.5	6.63	<b>0.23</b>	3.9
* Roche Cobas Integra 800	111	8.55	<b>0.05</b>	3.3	<b>5.61</b>	<b>0.21</b>	3.0	6.57	<b>0.17</b>	3.1
* Roche/Hitachi Modular P	14	8.26	<b>-0.24</b>	5.5	<b>5.41</b>	<b>0.01</b>	3.9	6.31	<b>-0.09</b>	4.0
Siemens Advia	48	8.51	<b>0.01</b>	3.3	<b>5.49</b>	<b>0.09</b>	3.8	6.54	<b>0.14</b>	3.9
Siemens Advia New Reagent	25	8.48	<b>-0.02</b>	3.3	<b>5.42</b>	<b>0.02</b>	3.9	6.47	<b>0.07</b>	4.2
Siemens Advia Original Reagent	21	8.54	<b>0.04</b>	2.8	<b>5.57</b>	<b>0.17</b>	3.1	6.62	<b>0.22</b>	3.3
* Siemens DCA 2000/2000+	66	8.50	<b>0.00</b>	3.1	<b>5.47</b>	<b>0.07</b>	2.9	6.54	<b>0.14</b>	2.7
* Siemens DCA Vantage	162	8.39	<b>-0.11</b>	2.7	<b>5.48</b>	<b>0.08</b>	2.4	6.52	<b>0.12</b>	2.5
* Siemens Dimension ExL	59	8.55	<b>0.05</b>	3.0	<b>5.72</b>	<b>0.32</b>	2.5	6.55	<b>0.15</b>	2.9
* ExL original reagent	44	8.58	<b>0.08</b>	3.1	<b>5.71</b>	<b>0.31</b>	2.3	6.55	<b>0.15</b>	2.6
* Siemens Dimension RxL	236	8.47	<b>-0.03</b>	2.8	<b>5.69</b>	<b>0.29</b>	2.7	6.53	<b>0.13</b>	2.7
* RxL original reagent	178	8.48	<b>-0.02</b>	2.7	<b>5.69</b>	<b>0.29</b>	2.7	6.53	<b>0.13</b>	2.7
* Siemens Dimension Vista	125	8.75	<b>0.25</b>	2.3	<b>5.39</b>	<b>-0.01</b>	2.8	6.66	<b>0.26</b>	4.2
* Vista original reagent	105	8.75	<b>0.25</b>	2.2	<b>5.39</b>	<b>-0.01</b>	2.8	6.64	<b>0.24</b>	4.0
* Siemens Dimension Xpand	108	8.43	<b>-0.07</b>	2.9	<b>5.67</b>	<b>0.27</b>	3.1	6.46	<b>0.06</b>	3.4
* Xpand original reagent	69	8.43	<b>-0.07</b>	2.9	<b>5.66</b>	<b>0.26</b>	3.0	6.42	<b>0.02</b>	3.6
* Tosoh G7 Auto HPLC	170	8.73	<b>0.23</b>	1.7	<b>5.56</b>	<b>0.16</b>	1.6	6.57	<b>0.17</b>	2.1
* Tosoh G8 Auto HPLC	186	8.69	<b>0.19</b>	1.7	<b>5.53</b>	<b>0.13</b>	1.5	6.56	<b>0.16</b>	1.4
* Trinity Biotech HPLC (Affinity)	19	8.58	<b>0.08</b>	2.6	<b>5.57</b>	<b>0.17</b>	3.0	6.46	<b>0.06</b>	1.8
* Vitros 5,1 FS Chem System	155	8.71	<b>0.21</b>	3.5	<b>5.48</b>	<b>0.08</b>	3.6	6.56	<b>0.16</b>	3.3

\* = NGSP certified at the time of the survey

<sup>t</sup> Assigned as the mean of 3 replicate analyses per day for two days per method using 7 NGSP certified secondary reference methods.

<sup>#</sup> 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

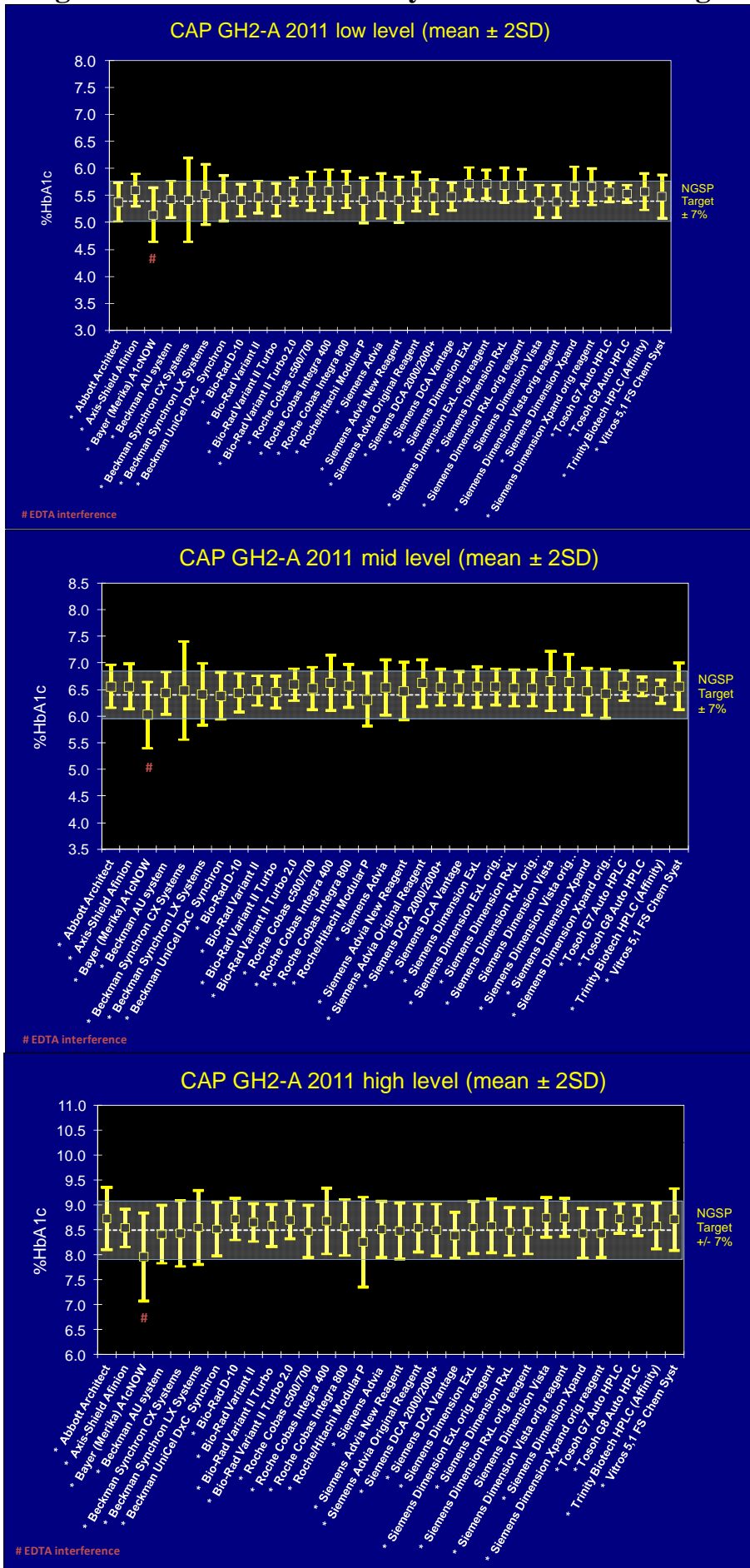
Gray shading indicates bias > 0.3% HbA1c or CV > 5% (except Bayer A1cNow bias)

In 2011, based on data from the GH2-A survey:

- Bias from the NGSP target and variability ( $\pm 2SD$ ) are shown in the table above and in figure 1 for each method. The shaded rectangle (fig 1) reflects the current CAP acceptance limit of  $\pm 7\%$ . Other than the Bayer A1cNow<sup>#</sup> (see footnote above), the method-specific means were all within 0.35 for all HbA1c levels (table above). Only one method had a bias over 0.3% HbA1c (Siemens Dimension ExL, low HbA1c level).
- Method-specific, between-laboratory CV's ranged from 1.4% to 7.2%. All but 3 methods had CVs below 5% for all three levels. Approximately 97% of laboratories were using methods that had between-lab CVs  $< 5.0\%$  at all three HbA1c levels, and almost 50% are using methods with CVs  $< 3\%$  at all three HbA1c levels.
- The current pass limit for the GH2 survey is  $\pm 7\%$ . The overall pass rate for this survey was 92.8, 95.2 and 95.2% of labs passing for the low, mid and high samples, respectively. For individual methods, the lowest pass rate was 64.3% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH2-A 2011). 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.
- The overall CVs for all methods in all laboratories have decreased over the last few years. The overall CVs for the last three surveys are shown in Table 1. The 2011-A survey all-method CVs are between 3.2 and 3.5%! There continues to be a few methods with either high CVs or high bias or both. But there are also many methods that show consistent good performance.

*NOTE: The NGSP certification evaluates agreement of each method 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 800) 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 laboratories review not only the certification status of HbA1c methods but also their performance in the CAP survey over time (a good indication of field performance) when selecting or evaluating HbA1c assay methods.*

**Figure 1: Bias and Variability from the NGSP Target**



**Table 1: Overall Variability for 2010-2011 for all GH2 participants**

<b>Mailing</b>	<b>Sample#</b>	<b># of labs</b>	<b>Target</b>	<b>All method mean</b>	<b>S.D.</b>	<b>C.V.</b>
A-2010	01	2573	5.9	6.03	0.23	3.9
	02	2566	9.8	9.73	0.39	4.0
	03	2581	7.4	7.43	0.31	4.2
B-2010	04	2693	5.2	5.34	0.21	4.0
	05	2691	8.7	8.67	0.33	3.8
	06	2685	6.3	6.37	0.23	3.5
A-2011	01	2652	8.5	8.58	0.28	3.2
	02	2645	5.4	5.52	0.20	3.5
	03	2649	6.4	6.51	0.21	3.2