College of American Pathologists (CAP) GH5 Survey Data:

(updated 5/15)

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 GH5 data for the **first** survey of 2015 are summarized below. The NGSP target or reference values are based on replicate analyses using seven NGSP certified secondary reference methods.

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

Beginning with this survey there are two CAP programs for HbA1c proficiency testing using fresh whole blood samples - GH2 and GH5. GH2 samples will be shipped twice a year with three samples in each mailing as before. GH5 will be shipped three times a year with five samples in each mailing. The three samples in each of the two GH2 mailings will also be included in two of the GH5 mailings. Therefore the NGSP will follow the three GH5 surveys which will include all the samples used for both surveys.

In 2015, based on data from the GH5-A survey:

- **Note that GH5-04 and 05 had fewer laboratories participating; these samples were only included in GH5 and not GH2.**
- **Note that GH5-01 and 03 were the same pooled whole blood sample.**
- **Bias from the NGSP target and variability (±2SD) are shown in Table 1 and in figure 1 for each method. The shaded rectangle (fig 1) reflects the current CAP acceptance limit of ±6. The method-specific biases were > 0.30 for three of the 5 HbA1c samples for the Ortho Clinical Diagnostics Vitros method. The DCA Vantage had bias >0.30 for 2; Beckman AU and G7 each had bias >0.30 for 1. All biases for the remaining methods were ≤0.3%**
- **Method-specific, between-laboratory CV's ranged from 1.1% to 8.5%. One method (Abbott Architect i immunoassay) had CVs over 5% for all samples, three additional methods each had one CV >4% (Beckman AU, Siemens Advia, Roche cobas c311). The lowest CVs (≤2% for at least 4 samples) were seen for the Tosoh G8, the Trinity Biotech HPLC (not Premier) and the new Abbott Architect c System enzymatic method. The Architect enzymatic and Trinity Biotech HPLC methods were the only methods to show CVs ≤2% for all five samples. Over 60% of laboratories are using methods with CVs <3% at all five HbA1c levels; over 76% of laboratories are using methods with CVs ≤3.5% at all five HbA1c levels.**
- **The current pass limit for the GH2 survey is ±6%. The overall pass rates for this survey were 94.3, 93.3, 94.2, 94.0, and 96.3 % of labs passing for GH5-01 through 05, respectively. For individual methods, the lowest pass rate was 62.9% and the highest was 100% (Sacks, Chemistry Resource Committee, CAP GH5-A 2015). As expected, 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 the last ten surveys are shown in Table 2. We are hovering around our goal of ≤3.5%.**
- **As mentioned above, GH5-01 and 03 are from the same sample pool. Figure 2 shows the means of the absolute differences between these duplicates for each method. All of the mean differences between duplicates were below 0.2% HbA1c!**
- **Many people ask why NGSP certified methods do not always perform well on the CAP survey. The note below is included with each survey commentary and addresses this question. Related to this, I**

have also removed the "*" notation in the data table indicating the methods that are NGSP certified because it may have been a bit misleading. In many cases, only some method applications under the method listed has passed certification, i.e. for some methods there are several applications and not all of them have necessarily passed certification.

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.

TABLE 1: 2015 GH5-A (fresh pooled samples)

		GH5-01			GH5-02			GH5-03				GH5-04			GH5-05		
[t] NGSP %HbA1c Reference Value (95% CI)		6.79 (6.72-6.86)			10.28 (10.20-10.36)			6.82 (6.75-6.88)				8.63 (8.56-8.70)			5.32 (5.25-5.39)		
	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV	no. labs	Mean %HbA1c	Mean bias	% CV	Mean %HbA1c	Mean bias	% CV
Abbott Architect c	42	6.90	0.11	3.0	10.35	0.07	3.8	6.92	0.10	2.9	26	8.74	0.11	2.7	5.41	0.09	3.0
Abbott Architect c (enzymatic)	42	6.66	-0.13	1.5	10.15	-0.13	1.3	6.66	-0.16	1.4	32	8.55	-0.08	1.1	5.18	-0.14	1.7
Abbott Architect i	35	6.85	0.06	6.4	10.28	0.00	8.4	6.86	0.04	8.0	28	8.79	0.16	8.5	5.47	0.15	8.1
Axis-Shield Afinion	54	6.79	0.00	2.4	10.16	-0.12	2.8	6.86	0.04	2.3	15	8.43	-0.20	2.3	5.39	0.07	3.5
Beckman AU	65	6.67	-0.12	4.3	10.00	-0.28	3.9	6.68	-0.14	3.9	40	8.29	-0.34	3.6	5.17	-0.15	3.1
Beckman UniCel DxC	149	6.78	-0.01	2.6	10.37	0.09	3.1	6.77	-0.05	2.5	114	8.70	0.07	2.6	5.31	-0.01	2.5
Bio-Rad D-10	198	6.92	0.13	2.7	10.36	0.08	2.3	6.92	0.10	2.4	136	8.72	0.09	2.3	5.36	0.04	2.6
Bio-Rad VII	70	6.90	0.11	2.6	10.43	0.15	2.6	6.92	0.10	2.9	60	8.77	0.14	2.7	5.29	-0.03	2.9
Bio-Rad VII Turbo	104	6.79	0.00	3.2	10.33	0.05	2.5	6.82	0.00	3.0	85	8.69	0.06	2.5	5.30	-0.02	2.9
Bio-Rad VII Turbo 2.0	144	6.89	0.10	2.3	10.26	-0.02	2.5	6.88	0.06	2.6	121	8.67	0.04	2.7	5.25	-0.07	2.7
Roche Cobas c311	30	6.80	0.01	2.7	10.39	0.11	2.6	6.78	-0.04	2.7	19	8.73	0.10	2.8	5.35	0.03	4.1
Roche Cobas c500 series	358	6.77	-0.02	2.7	10.01	-0.27	2.8	6.76	-0.06	2.5	293	8.51	-0.12	2.9	5.39	0.07	2.8
Roche Cobas Integra 400	58	6.78	-0.01	3.2	10.09	-0.19	3.7	6.83	0.01	3.3	24	8.71	0.08	3.3	5.36	0.04	3.4
Roche Cobas Integra 800	125	6.80	0.01	2.7	10.28	0.00	2.6	6.81	-0.01	2.2	110	8.67	0.04	2.3	5.48	0.16	2.5
Sebia Capillarys 2/ Minicap	20	6.62	-0.17	1.6	10.04	-0.24	2.5	6.60	-0.22	2.1	12	8.58	-0.05	1.7	5.14	-0.18	2.7
Siemens Advia	29	6.93	0.14	4.0	10.09	-0.19	4.9	6.88	0.06	2.9	25	8.64	0.01	2.9	5.36	0.04	3.7
Siemens DCA 2000/2000+	26	6.67	-0.12	2.7	10.21	-0.07	3.2	6.67	-0.15	2.9	<10						
Siemens DCA Vantage	340	6.60	-0.19	2.7	9.90	-0.38	3.3	6.61	-0.21	2.7	145	8.31	-0.32	2.8	5.22	-0.10	2.7
Siemens Dimension ExL	193	6.89	0.10	3.5	10.23	-0.05	3.4	6.92	0.10	3.2	128	8.65	0.02	2.9	5.43	0.11	3.7
Siemens Dimension RxL	38	6.95	0.16	2.2	10.32	0.04	2.5	6.91	0.09	2.5	23	8.71	0.08	2.7	5.43	0.11	3.7
Siemens Dimension Vista	259	6.98	0.19	2.5	10.16	-0.12	2.6	6.97	0.15	2.6	232	8.63	0.00	2.8	5.45	0.13	2.6
Siemens Dimension Xpand	47	6.94	0.15	2.8	10.28	0.00	3.5	6.93	0.11	3.0	21	8.67	0.04	2.9	5.50	0.18	3.8
Tosoh G7 Auto HPLC	73	7.09	0.30	2.4	10.51	0.23	2.3	7.09	0.27	2.6	52	8.95	0.32	2.6	5.48	0.16	2.7
Tosoh G8 Auto HPLC	330	7.05	0.26	2.1	10.50	0.22	1.9	7.06	0.24	1.9	287	8.93	0.30	1.9	5.45	0.13	1.9
Trinity Biotech HPLC	14	6.66	-0.13	1.5	10.26	-0.02	1.9	6.68	-0.14	1.9	13	8.50	-0.13	1.9	5.31	-0.01	2.0
Trinity Biotech Premier	60	6.74	-0.05	2.3	10.22	-0.06	2.3	6.83	0.01	2.3	54	8.54	-0.09	1.9	5.35	0.03	2.2
(Ortho Clin Diag) Vitros 5,1 FS, 4600, 5600	191	6.46	-0.33	2.5	9.90	-0.38	2.7	6.47	-0.35	2.5	151	8.33	-0.30	2.5	5.17	-0.15	2.8

[t] Assigned as the mean of 3 replicate analyses per day for two days per method using 6 NGSP certified secondary reference methods.

Gray shading indicates bias > 0.3% HbA1c or CV > 4% Note: these are arbitrary limits chosen to highlight methods with the highest bias and CV.

Figure 1: Bias and Variability from the NGSP Target

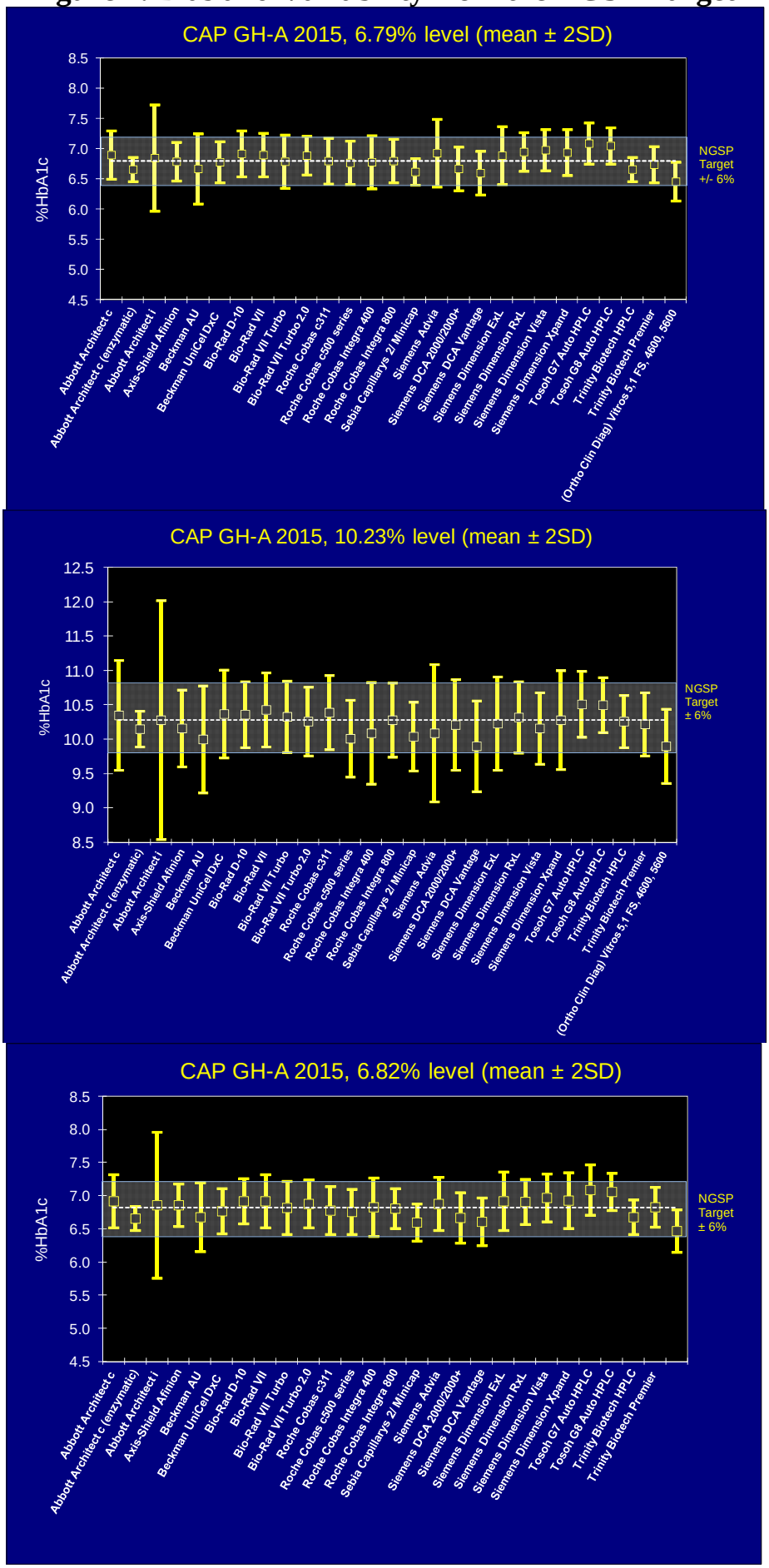
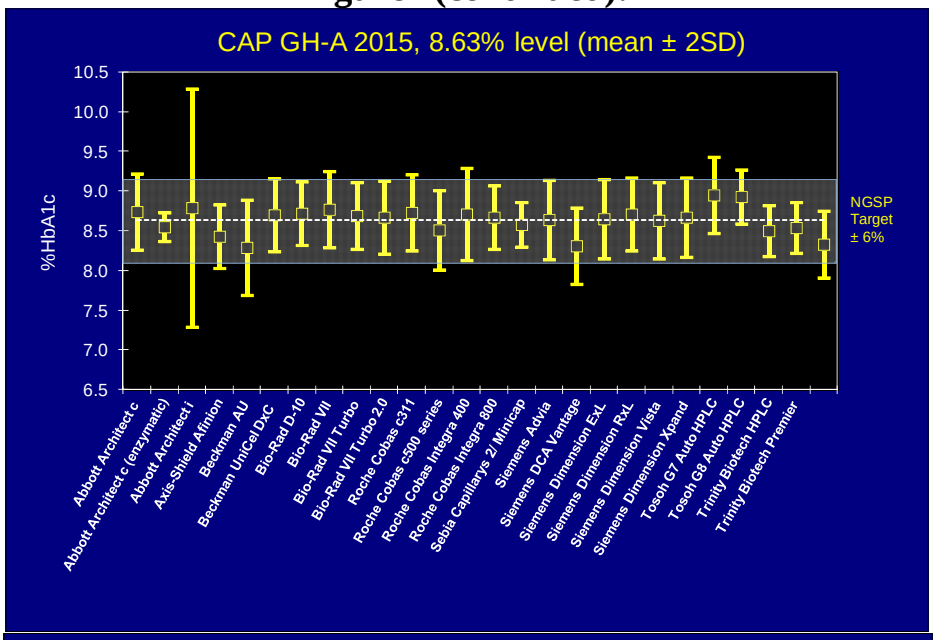


Figure 1(continued):



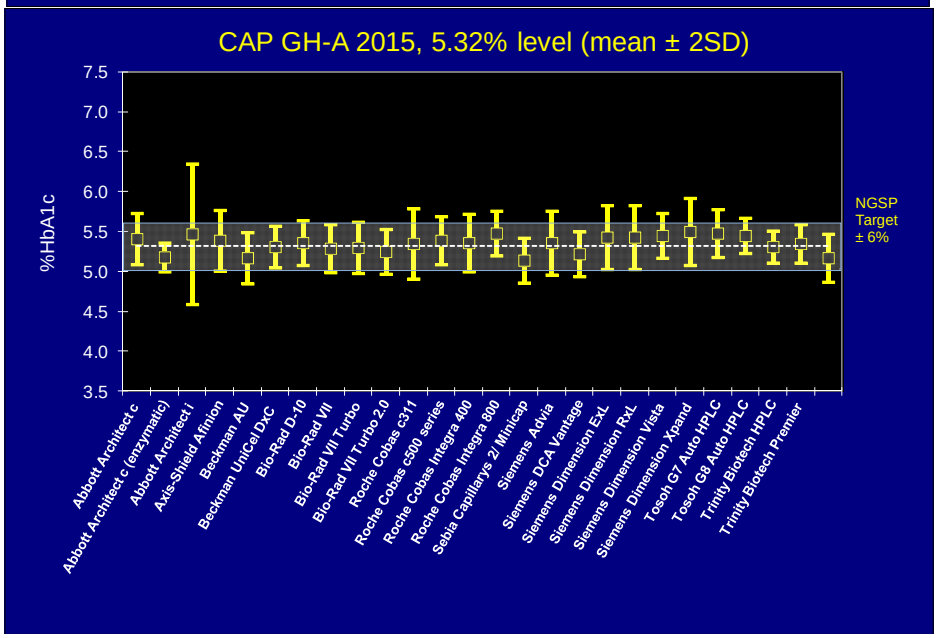
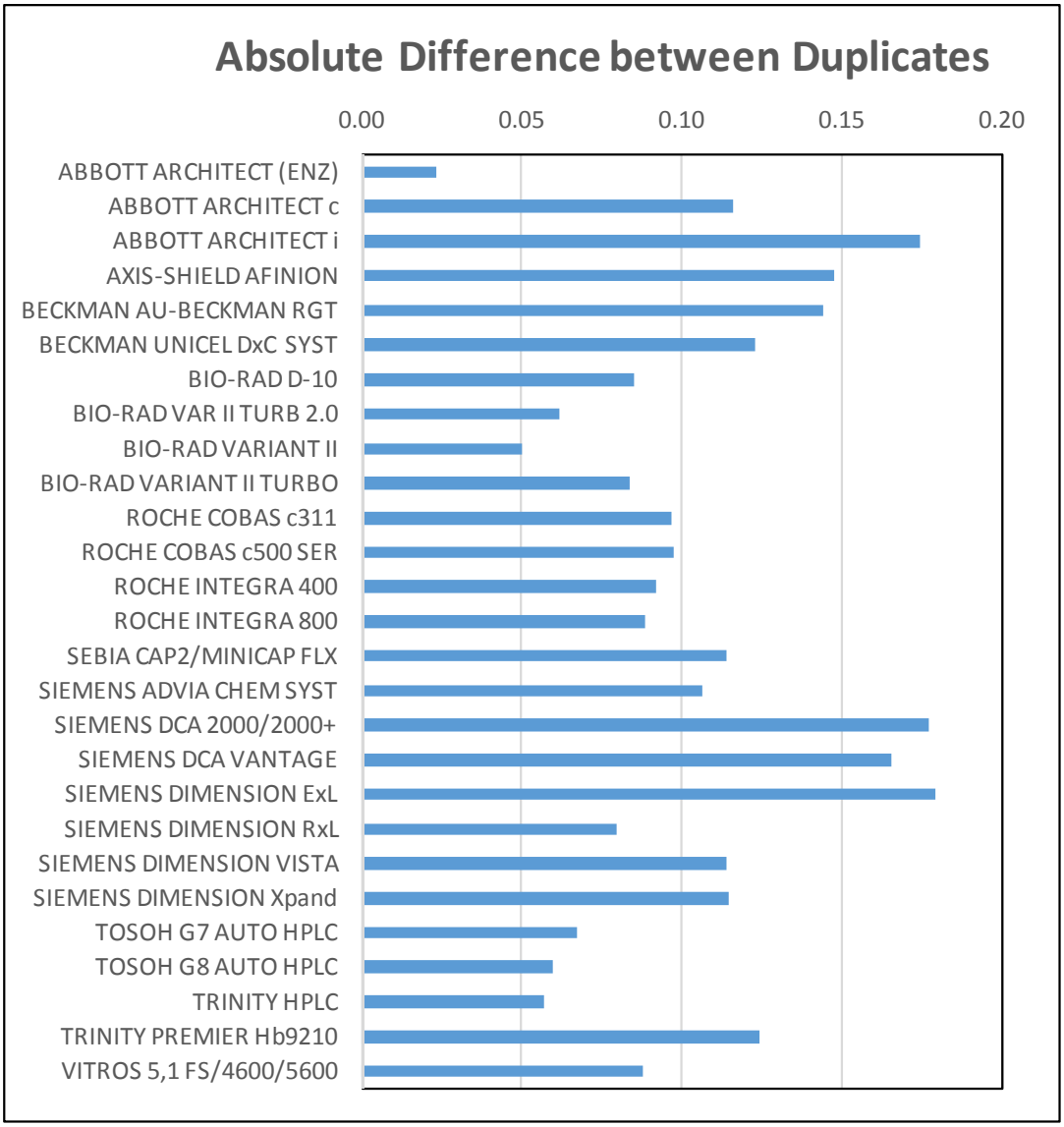


Table 2: Overall Variability for 2010-2015 for all GH participants

Mailing	Sample#	# of labs	Target	All method mean	S.D.	C.V.
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
B-2011	04	2877	6.3	6.36	0.24	3.8
	05	2872	7.6	7.69	0.29	3.8
	06	2871	9.2	9.28	0.34	3.7
A 2012	01	3298	5.6	5.62	0.20	3.5
	02	3316	9.4	9.44	0.37	3.9
	03	3301	7.2	7.28	0.29	3.9
B2012	04	3222	5.4	5.51	0.21	3.9
	05	3208	8.3	8.31	0.31	3.7
(HbAS)	06	3172	5.65	5.75	0.32	5.6
A 2013	01	2816	7.1	7.12	0.25	3.5
	02	2829	9.3	9.39	0.31	3.3
	03	2840	6.1	6.13	0.24	3.9
B2013	04	2912	8.1	8.04	0.31	3.8
	05	2907	5.3	5.33	0.20	3.8
	06	2908	6.4	6.17	0.24	3.9
A2014	01	3277	6.5	6.60	0.25	3.8
	02	3267	7.0	7.09	0.27	3.8
	03	3253	9.7	9.72	0.33	3.4
B2014	04	3278	6.58	6.64	0.23	3.5
	05	3273	8.39	8.45	0.30	3.6
	06	3266	5.65	5.67	0.21	3.6
A2015	01	3237	6.79	6.82	0.25	3.6
	02	3246	10.28	10.19	0.36	3.5
	03	3252	6.82	6.82	0.25	3.6
	04	2365	8.63	8.63	0.30	3.4
	05	2362	5.32	5.36	0.18	3.4

Figure 2:


Absolute Difference between Duplicates
0.00
0.05
0.10
0.15
0.20
ABBOTT ARCHITECT (ENZ)
ABBOTT ARCHITECT c
ABBOTT ARCHITECT i
AXIS-SHIELD AFINION
BECKMAN AU-BECKMAN RGT
BECKMAN UNICEL DxC SYST
BIO-RAD D-10
BIO-RAD VAR II TURB 2.0
BIO-RAD VARIANT II
BIO-RAD VARIANT II TURBO
ROCHE COBAS c311
ROCHE COBAS c500 SER
ROCHE INTEGRA 400
ROCHE INTEGRA 800
SEBIA CAP2/MINICAP FLX
SIEMENS ADVIA CHEM SYST
SIEMENS DCA 2000/2000+
SIEMENS DCA VANTAGE
SIEMENS DIMENSION ExL
SIEMENS DIMENSION RxL
SIEMENS DIMENSION VISTA
SIEMENS DIMENSION Xpand
TOSOH G7 AUTO HPLC
TOSOH G8 AUTO HPLC
TRINITY HPLC
TRINITY PREMIER Hb9210
VITROS 5,1 FS/4600/5600