

NGSP Administrative Core

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August 5, 2011

Susan Sun
 COVANCE ASIA PTE LTD
 1 INTERNATIONAL BUSINESS PARK
 #05-13 THE SYNERGY SINGAPORE 609917

Dear Dr. Sun,

Congratulations! We are pleased to inform you that COVANCE ASIA PTE LTD has successfully completed the NGSP **Level I Laboratory** certification for the following method:

Instrument: Variant II	Calibrator Lot: AN02104NU, AN02105NU	Column Lot: 92450
Reagent Lot: AA10283NU, AA10284NU, AA10285NU, AA10364NU	Calibrator Assigned Values: 5.6%, 10.1%	

The above method is now considered traceable to the Diabetes Control and Complications Trial (DCCT) Reference Method. Enclosed is a certificate of traceability for this method.

Following is a summary of the method comparison results. Detailed method comparison evaluation reports are also enclosed for your information.

Method	Assessment of Agreement CI; lower 95%, upper 95% (limit $\pm 0.70\%$)
Covance Asia, Singapore, VII	-0.21, 0.26

Column 2, Assessment of Agreement CI of diff, lower and upper 95%; (limit $\pm 0.70\%$):
 95% Confidence Interval of the differences between methods (test method vs. SRL) must fall within the clinically significant limits of $\pm 0.75\%$ HbA1c for manufacturer methods and Level II Laboratory methods, $\pm 0.70\%$ for Level I Laboratory methods. **Your method's results were within the NGSP assessment of agreement criteria for Level I Laboratory Certification.**

This certification is effective for one year and will expire on September 1, 2012. All data for next year's certification should be received by July, 2012. Your next set of quarterly monitoring samples is tentatively scheduled for October.



Certificate of Traceability

Level I Laboratory Certification

This certifies that Covance Asia Pte Ltd, using Bio-Rad Variant II has participated in and successfully completed NGSP Level I Laboratory certification and is traceable to the **Diabetes Control and Complications Trial** Reference method. The comparison was performed with: University of Missouri SRL#9

The system evaluated was:

Instrument: Variant II	Calibrator Lot: AN02104NU, AN02105NU	Column Lot: 92450
Reagent Lot: AA10283NU, AA10284NU, AA10285NU, AA10364NU	Calibrator Assigned Values: 5.6%, 10.1%	

Date of Certification: September 1, 2011

Certification Expires: September 1, 2012

Handwritten signature of David Sault.

NGSP Steering Committee Chair

Handwritten signature of Sandra R. Little PhD.

NGSP Network Coordinator

Handwritten signature of Sharon Ansell.

SRL director/ supervisor

NATIONAL GLYCOHEMOGLOBIN STANDARDIZATION PROGRAM



**Method Comparison Evaluation
Assessment of Agreement Report**

Level 1 Laboratory: Covance Asia Pte Ltd Certification Type: Level 1 Laboratory
 Test Method (Y): Variant II
 Comparative Method (X): SRL#9 Tosoh G8 Report Date: 08/02/11

Sample ID	Assay Date	X1	X2	Y1	Y2	Mean X	Y1-Mean X	Y2-Mean X
7037	07/25/11	4.80	4.80	4.90	4.90	4.80	0.10	0.10
7038	07/25/11	9.10	9.10	9.20	9.20	9.10	0.10	0.10
7039	07/25/11	8.30	8.30	8.20	8.30	8.30	-0.10	0.00
7040	07/25/11	10.10	10.00	10.00	10.10	10.05	-0.05	0.05
7041	07/25/11	8.50	8.50	8.50	8.50	8.50	0.00	0.00
7042	07/25/11	7.40	7.30	7.40	7.40	7.35	0.05	0.05
7043	07/25/11	4.90	4.90	4.90	4.90	4.90	0.00	0.00
7044	07/25/11	6.20	6.20	6.40	6.40	6.20	0.20	0.20
7045	07/26/11	9.20	9.30	9.40	9.40	9.25	0.15	0.15
7046	07/26/11	4.80	4.80	4.90	4.90	4.80	0.10	0.10
7047	07/26/11	9.00	9.00	9.00	9.00	9.00	0.00	0.00
7048	07/26/11	5.50	5.50	5.60	5.60	5.50	0.10	0.10
7049	07/26/11	8.40	8.40	8.50	8.50	8.40	0.10	0.10
7050	07/26/11	6.10	6.10	6.30	6.30	6.10	0.20	0.20
7051	07/26/11	7.50	7.50	7.70	7.70	7.50	0.20	0.20
7052	07/26/11	6.20	6.10	6.20	6.30	6.15	0.05	0.15
7053	07/27/11	9.10	9.10	9.30	9.30	9.10	0.20	0.20
7054	07/27/11	10.10	10.00	9.60	9.70	10.05	-0.45	-0.35
7055	07/27/11	8.20	8.10	8.20	8.20	8.15	0.05	0.05
7056	07/27/11	8.60	8.60	8.50	8.60	8.60	-0.10	0.00
7057	07/27/11	5.20	5.20	5.30	5.30	5.20	0.10	0.10
7058	07/27/11	7.90	7.90	7.90	7.80	7.90	0.00	-0.10
7059	07/27/11	5.80	5.80	5.80	5.80	5.80	0.00	0.00
7060	07/27/11	6.70	6.70	6.70	6.60	6.70	0.00	-0.10
7061	07/28/11	4.70	4.70	4.60	4.70	4.70	-0.10	0.00
7062	07/28/11	5.40	5.40	5.30	5.30	5.40	-0.10	-0.10
7063	07/28/11	7.70	7.70	7.70	7.70	7.70	0.00	0.00
7064	07/28/11	5.00	5.00	5.00	5.00	5.00	0.00	0.00
7065	07/28/11	6.10	6.10	6.00	5.90	6.10	-0.10	-0.20
7066	07/28/11	5.20	5.20	5.30	5.30	5.20	0.10	0.10
7067	07/28/11	7.60	7.60	7.60	7.60	7.60	0.00	0.00
7068	07/28/11	8.10	8.10	8.10	8.20	8.10	0.00	0.10
7069	07/29/11	4.80	4.80	4.80	4.80	4.80	0.00	0.00
7070	07/29/11	8.20	8.10	8.30	8.30	8.15	0.15	0.15
7071	07/29/11	6.70	6.70	6.50	6.60	6.70	-0.20	-0.10
7072	07/29/11	7.20	7.10	7.20	7.20	7.15	0.05	0.05
7073	07/29/11	5.70	5.70	5.70	5.70	5.70	0.00	0.00
7074	07/29/11	7.40	7.40	7.50	7.50	7.40	0.10	0.10
7075	07/29/11	5.70	5.70	5.60	5.60	5.70	-0.10	-0.10
7076	07/29/11	6.20	6.10	6.10	6.10	6.15	-0.05	-0.05

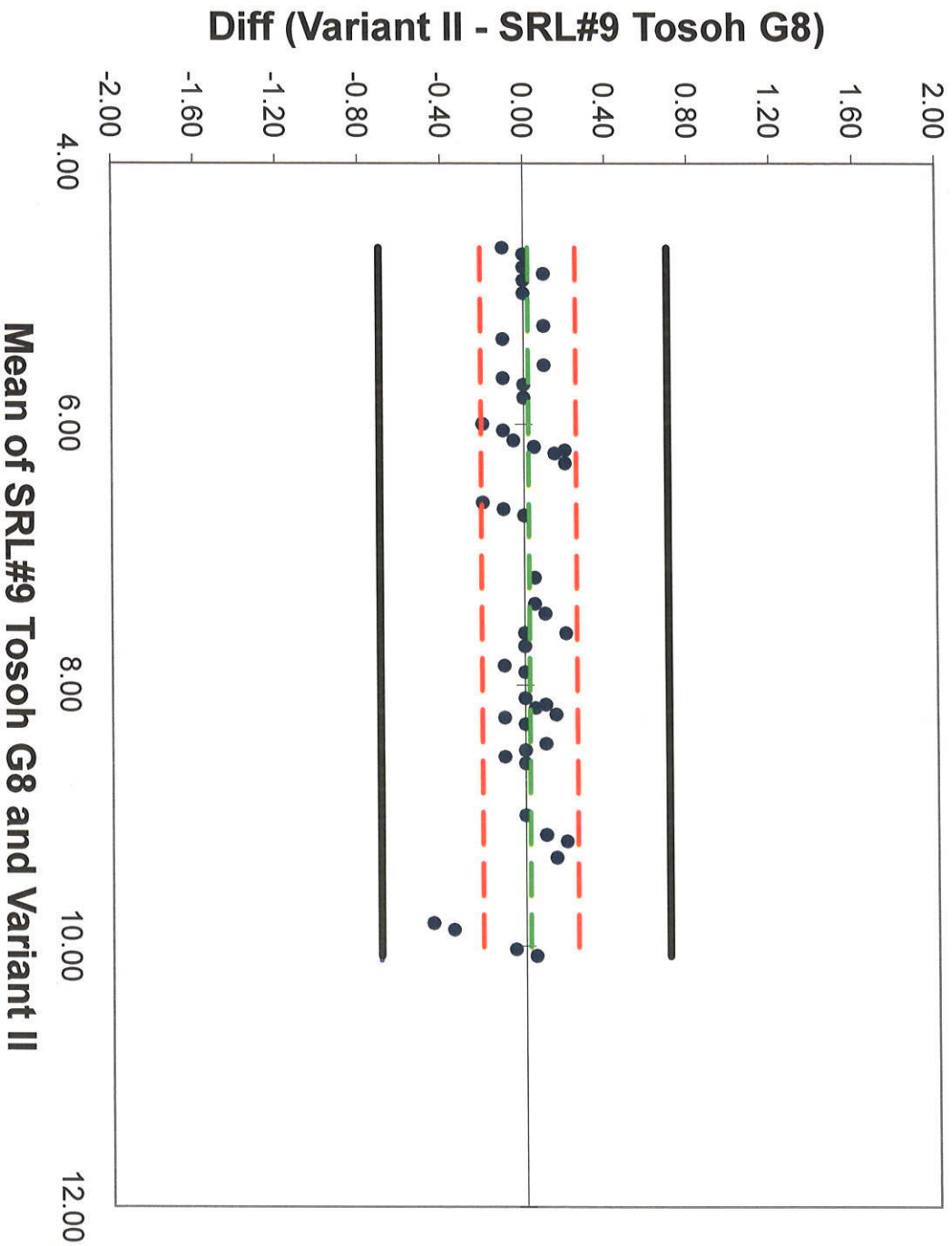
n=	80
Mean (Y-Mean X)	0.03
sd (Y-Mean X)	0.118

Confidence Interval	Y- (Mean X)	Acceptable Limit	Pass/Fail
Lower 95%	-0.21	-0.70	Pass
Upper 95%	0.26	+0.70	Pass



Level I Assessment of Agreement

Covance Asia Pte Ltd Variant II





Method Comparison Evaluation Within and Between Method Outlier Report (For Investigational Use Only)

Level 1 Laboratory: Covance Asia Pte Ltd Certification Type: Level 1 Laboratory
 Test Method (Y): Variant II
 Comparative Method (X): SRL#9 Tosoh G8 Report Date: 08/02/11

Sample ID	Assay Date	Mean X	Y1	Y2	Mean Y	Differences		Outliers	
						Between	Within	Between	Within
						Mean Y-Mean X	ABS Y2-Y1	Mean Y-Mean X	Y2-Y1
7037	07/25/11	4.80	4.90	4.90	4.90	0.10	0.00		
7038	07/25/11	9.10	9.20	9.20	9.20	0.10	0.00		
7039	07/25/11	8.30	8.20	8.30	8.25	-0.05	0.10		
7040	07/25/11	10.05	10.00	10.10	10.05	0.00	0.10		
7041	07/25/11	8.50	8.50	8.50	8.50	0.00	0.00		
7042	07/25/11	7.35	7.40	7.40	7.40	0.05	0.00		
7043	07/25/11	4.90	4.90	4.90	4.90	0.00	0.00		
7044	07/25/11	6.20	6.40	6.40	6.40	0.20	0.00		
7045	07/26/11	9.25	9.40	9.40	9.40	0.15	0.00		
7046	07/26/11	4.80	4.90	4.90	4.90	0.10	0.00		
7047	07/26/11	9.00	9.00	9.00	9.00	0.00	0.00		
7048	07/26/11	5.50	5.60	5.60	5.60	0.10	0.00		
7049	07/26/11	8.40	8.50	8.50	8.50	0.10	0.00		
7050	07/26/11	6.10	6.30	6.30	6.30	0.20	0.00		
7051	07/26/11	7.50	7.70	7.70	7.70	0.20	0.00		
7052	07/26/11	6.15	6.20	6.30	6.25	0.10	0.10		
7053	07/27/11	9.10	9.30	9.30	9.30	0.20	0.00		
7054	07/27/11	10.05	9.60	9.70	9.65	-0.40	0.10	outlier	
7055	07/27/11	8.15	8.20	8.20	8.20	0.05	0.00		
7056	07/27/11	8.60	8.50	8.60	8.55	-0.05	0.10		
7057	07/27/11	5.20	5.30	5.30	5.30	0.10	0.00		
7058	07/27/11	7.90	7.90	7.80	7.85	-0.05	0.10		
7059	07/27/11	5.80	5.80	5.80	5.80	0.00	0.00		
7060	07/27/11	6.70	6.70	6.60	6.65	-0.05	0.10		
7061	07/28/11	4.70	4.60	4.70	4.65	-0.05	0.10		
7062	07/28/11	5.40	5.30	5.30	5.30	-0.10	0.00		
7063	07/28/11	7.70	7.70	7.70	7.70	0.00	0.00		
7064	07/28/11	5.00	5.00	5.00	5.00	0.00	0.00		
7065	07/28/11	6.10	6.00	5.90	5.95	-0.15	0.10		
7066	07/28/11	5.20	5.30	5.30	5.30	0.10	0.00		
7067	07/28/11	7.60	7.60	7.60	7.60	0.00	0.00		
7068	07/28/11	8.10	8.10	8.20	8.15	0.05	0.10		
7069	07/29/11	4.80	4.80	4.80	4.80	0.00	0.00		
7070	07/29/11	8.15	8.30	8.30	8.30	0.15	0.00		
7071	07/29/11	6.70	6.50	6.60	6.55	-0.15	0.10		
7072	07/29/11	7.15	7.20	7.20	7.20	0.05	0.00		
7073	07/29/11	5.70	5.70	5.70	5.70	0.00	0.00		
7074	07/29/11	7.40	7.50	7.50	7.50	0.10	0.00		
7075	07/29/11	5.70	5.60	5.60	5.60	-0.10	0.00		
7076	07/29/11	6.15	6.10	6.10	6.10	-0.05	0.00		

	n	Mean	sd	3sd	Upper Limit	Lower Limit	Outliers
Between Method	40	0.025	0.115	0.346	0.371	-0.321	1
Within Method	40	0.028	0.045	0.136	0.163	N/A	0

Explanation:

Between-method outliers exceed the mean +/- 3sd of the differences between methods.
 Within-method outliers exceed the mean + 3sd of the absolute differences between replicates.



Scatter Plot

Covance Asia Pte Ltd Variant II

