

# Certificate of Traceability

## Level I Laboratory Certification

This certifies that Covance Central Laboratory (Shanghai), 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: <b>Variant II</b>	Calibrator Lot: AN02679NU, AN02680NU	Column Lot: NU6200AC
Reagent Lot: AA10597NU, AA10596NU, AA10059NU	Calibrator Assigned Values: 5.6%, 10.3%	

Date of Certification: September 1, 2011

Certification Expires: September 1, 2012

Handwritten signature of David Sacks.

NGSP Steering Committee Chair

Handwritten signature of Randie R. Little PhD.

NGSP Network Coordinator

Handwritten signature of Sharon Amick.

SRL director/ supervisor



## NGSP Administrative Core

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August 10, 2011

Marie-Line Palmero  
Covance Central Laboratory (Shanghai)  
1st Floor, No. 6 Bldg, No. 151 Li Bing Road  
Zhangjiang Hi-Tech Park  
Shanghai 201203  
China

Dear Dr. Palmero,

Congratulations! We are pleased to inform you that Covance Central Laboratory (Shanghai) has successfully completed the NGSP Level I Laboratory certification for the following method:

Instrument: <b>Variant II</b>	Calibrator Lot: <b>AN02679NU, AN02680NU</b>	Column Lot: <b>NU6200AC</b>
Reagent Lot: <b>AA10597NU, AA10596NU, AA10059NU</b>	Calibrator Assigned Values: <b>5.6%, 10.3%</b>	

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 Central Laboratory (Shanghai), China, VII	-0.06, 0.27

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.**

If you have any questions about any of the data, please feel free to call. If you or your customers would like updated information about the NGSP (including a list of certified methods and laboratories) they can visit our web site at [www.ngsp.org](http://www.ngsp.org)

Sincerely,

Randie R. Little, Ph.D.,  
NGSP Network Coordinator



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

Level I Laboratory: Covance Central Laboratory (Shanghai) Certification Type: Level I Laboratory  
 Test Method (Y): Variant II  
 Comparative Method (X): SRL#9 Tosoh G8 Report Date: 08/16/11

Sample ID	Assay Date	Mean X	Y1	Y2	Mean Y	Differences		Outliers	
						Between Mean Y-Mean X	Within ABS Y2-Y1	Between Mean Y-Mean X	Within Y2-Y1
CERT 7037	08/03/11	4.80	5.10	5.00	5.05	0.25	0.10		
CERT 7038	08/03/11	9.10	9.30	9.30	9.30	0.20	0.00		
CERT 7039	08/03/11	8.30	8.40	8.40	8.40	0.10	0.00		
CERT 7040	08/03/11	10.05	10.10	10.10	10.10	0.05	0.00		
CERT 7041	08/03/11	8.50	8.60	8.50	8.55	0.05	0.10		
CERT 7042	08/03/11	7.35	7.40	7.40	7.40	0.05	0.00		
CERT 7043	08/03/11	4.90	5.00	5.00	5.00	0.10	0.00		
CERT 7044	08/03/11	6.20	6.30	6.40	6.35	0.15	0.10		
CERT 7045	08/04/11	9.25	9.50	9.50	9.50	0.25	0.00		
CERT 7046	08/04/11	4.80	5.00	5.10	5.05	0.25	0.10		
CERT 7047	08/04/11	9.00	9.00	9.00	9.00	0.00	0.00		
CERT 7048	08/04/11	5.50	5.60	5.70	5.65	0.15	0.10		
CERT 7049	08/04/11	8.40	8.40	8.50	8.45	0.05	0.10		
CERT 7050	08/04/11	6.10	6.20	6.20	6.20	0.10	0.00		
CERT 7051	08/04/11	7.50	7.60	7.60	7.60	0.10	0.00		
CERT 7052	08/04/11	6.15	6.30	6.30	6.30	0.15	0.00		
CERT 7053	08/05/11	9.10	9.30	9.30	9.30	0.20	0.00		
CERT 7054	08/05/11	10.05	9.90	9.90	9.90	-0.15	0.00	outlier	
CERT 7055	08/05/11	8.15	8.20	8.30	8.25	0.10	0.10		
CERT 7056	08/05/11	8.60	8.60	8.60	8.60	0.00	0.00		
CERT 7057	08/05/11	5.20	5.40	5.40	5.40	0.20	0.00		
CERT 7058	08/05/11	7.90	8.00	8.00	8.00	0.10	0.00		
CERT 7059	08/05/11	5.80	5.90	5.90	5.90	0.10	0.00		
CERT 7060	08/05/11	6.70	6.80	6.80	6.80	0.10	0.00		
CERT 7061	08/06/11	4.70	4.80	4.80	4.80	0.10	0.00		
CERT 7062	08/06/11	5.40	5.50	5.50	5.50	0.10	0.00		
CERT 7063	08/06/11	7.70	7.80	7.80	7.80	0.10	0.00		
CERT 7064	08/06/11	5.00	5.30	5.20	5.25	0.25	0.10		
CERT 7065	08/06/11	6.10	6.10	6.10	6.10	0.00	0.00		
CERT 7066	08/06/11	5.20	5.40	5.40	5.40	0.20	0.00		
CERT 7067	08/06/11	7.60	7.70	7.70	7.70	0.10	0.00		
CERT 7068	08/06/11	8.10	8.20	8.20	8.20	0.10	0.00		
CERT 7069	08/08/11	4.80	4.90	4.90	4.90	0.10	0.00		
CERT 7070	08/08/11	8.15	8.30	8.20	8.25	0.10	0.10		
CERT 7071	08/08/11	6.70	6.80	6.80	6.80	0.10	0.00		
CERT 7072	08/08/11	7.15	7.20	7.30	7.25	0.10	0.10		
CERT 7073	08/08/11	5.70	5.80	5.80	5.80	0.10	0.00		
CERT 7074	08/08/11	7.40	7.40	7.40	7.40	0.00	0.00		
CERT 7075	08/08/11	5.70	5.70	5.80	5.75	0.05	0.10		
CERT 7076	08/08/11	6.15	6.30	6.30	6.30	0.15	0.00		

	n=	Mean	sd	3sd	Upper Limit	Lower Limit	Outliers
Between Method	40	0.108	0.081	0.242	0.349	-0.134	1
Within Method	40	0.028	0.045	0.136	0.163	N/A	0

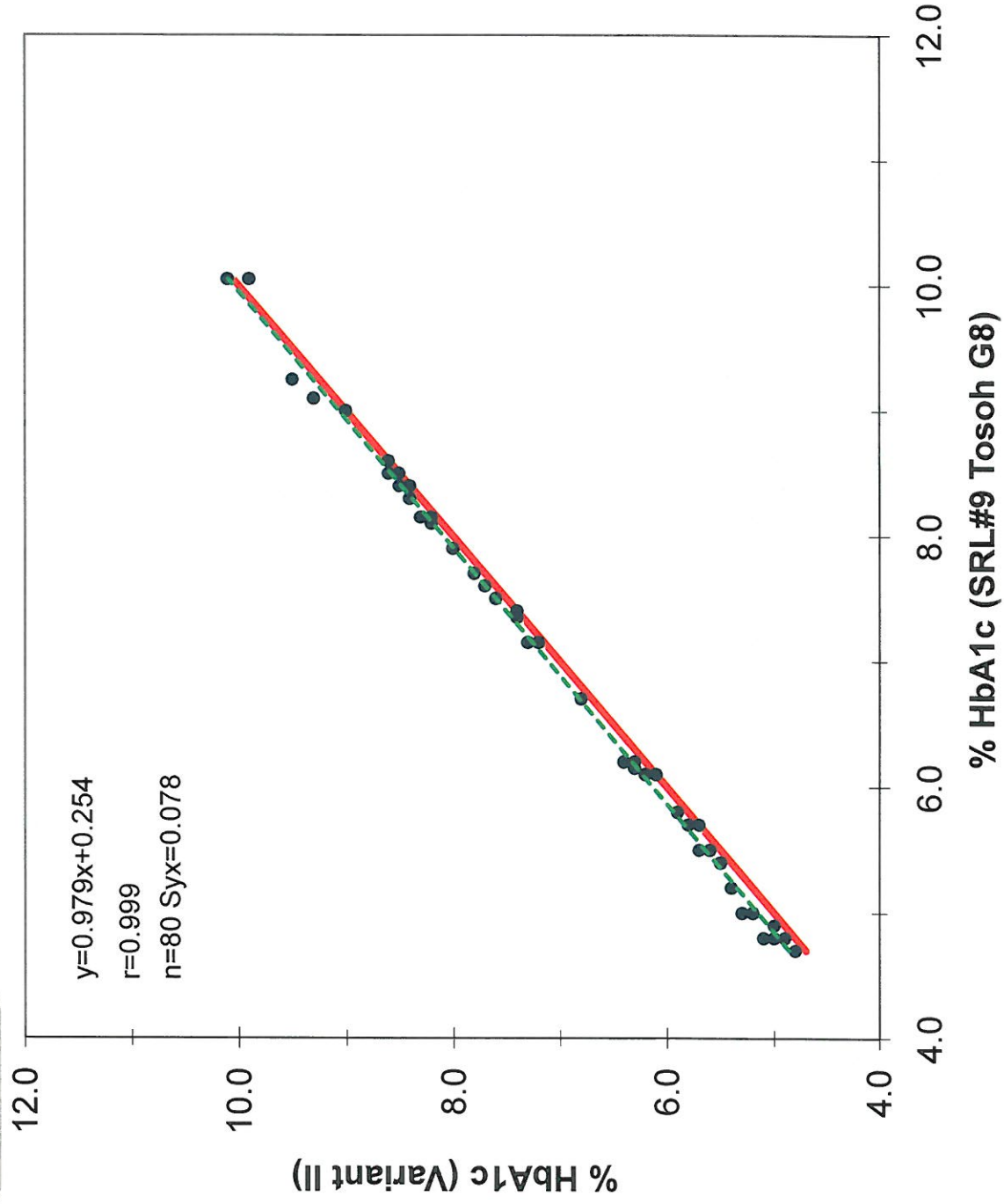
**Explanation:**

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 Central Laboratory (Shanghai) Variant II





**Method Comparison Evaluation  
Assessment of Agreement Report**

Level 1 Laboratory: Covance Central Laboratory (Shanghai) Certification Type: Level 1 Laboratory  
 Test Method (Y): Variant II  
 Comparative Method (X): SRL#9 Tosoh G8 Report Date: 08/16/11

Sample ID	Assay Date	X1	X2	Y1	Y2	Mean X	Y1-Mean X	Y2-Mean X
CERT 7037	08/03/11	4.80	4.80	5.10	5.00	4.80	0.30	0.20
CERT 7038	08/03/11	9.10	9.10	9.30	9.30	9.10	0.20	0.20
CERT 7039	08/03/11	8.30	8.30	8.40	8.40	8.30	0.10	0.10
CERT 7040	08/03/11	10.10	10.00	10.10	10.10	10.05	0.05	0.05
CERT 7041	08/03/11	8.50	8.50	8.60	8.50	8.50	0.10	0.00
CERT 7042	08/03/11	7.40	7.30	7.40	7.40	7.35	0.05	0.05
CERT 7043	08/03/11	4.90	4.90	5.00	5.00	4.90	0.10	0.10
CERT 7044	08/03/11	6.20	6.20	6.30	6.40	6.20	0.10	0.20
CERT 7045	08/04/11	9.20	9.30	9.50	9.50	9.25	0.25	0.25
CERT 7046	08/04/11	4.80	4.80	5.00	5.10	4.80	0.20	0.30
CERT 7047	08/04/11	9.00	9.00	9.00	9.00	9.00	0.00	0.00
CERT 7048	08/04/11	5.50	5.50	5.60	5.70	5.50	0.10	0.20
CERT 7049	08/04/11	8.40	8.40	8.40	8.50	8.40	0.00	0.10
CERT 7050	08/04/11	6.10	6.10	6.20	6.20	6.10	0.10	0.10
CERT 7051	08/04/11	7.50	7.50	7.60	7.60	7.50	0.10	0.10
CERT 7052	08/04/11	6.20	6.10	6.30	6.30	6.15	0.15	0.15
CERT 7053	08/05/11	9.10	9.10	9.30	9.30	9.10	0.20	0.20
CERT 7054	08/05/11	10.10	10.00	9.90	9.90	10.05	-0.15	-0.15
CERT 7055	08/05/11	8.20	8.10	8.20	8.30	8.15	0.05	0.15
CERT 7056	08/05/11	8.60	8.60	8.60	8.60	8.60	0.00	0.00
CERT 7057	08/05/11	5.20	5.20	5.40	5.40	5.20	0.20	0.20
CERT 7058	08/05/11	7.90	7.90	8.00	8.00	7.90	0.10	0.10
CERT 7059	08/05/11	5.80	5.80	5.90	5.90	5.80	0.10	0.10
CERT 7060	08/05/11	6.70	6.70	6.80	6.80	6.70	0.10	0.10
CERT 7061	08/06/11	4.70	4.70	4.80	4.80	4.70	0.10	0.10
CERT 7062	08/06/11	5.40	5.40	5.50	5.50	5.40	0.10	0.10
CERT 7063	08/06/11	7.70	7.70	7.80	7.80	7.70	0.10	0.10
CERT 7064	08/06/11	5.00	5.00	5.30	5.20	5.00	0.30	0.20
CERT 7065	08/06/11	6.10	6.10	6.10	6.10	6.10	0.00	0.00
CERT 7066	08/06/11	5.20	5.20	5.40	5.40	5.20	0.20	0.20
CERT 7067	08/06/11	7.60	7.60	7.70	7.70	7.60	0.10	0.10
CERT 7068	08/06/11	8.10	8.10	8.20	8.20	8.10	0.10	0.10
CERT 7069	08/08/11	4.80	4.80	4.90	4.90	4.80	0.10	0.10
CERT 7070	08/08/11	8.20	8.10	8.30	8.20	8.15	0.15	0.05
CERT 7071	08/08/11	6.70	6.70	6.80	6.80	6.70	0.10	0.10
CERT 7072	08/08/11	7.20	7.10	7.20	7.30	7.15	0.05	0.15
CERT 7073	08/08/11	5.70	5.70	5.80	5.80	5.70	0.10	0.10
CERT 7074	08/08/11	7.40	7.40	7.40	7.40	7.40	0.00	0.00
CERT 7075	08/08/11	5.70	5.70	5.70	5.80	5.70	0.00	0.10
CERT 7076	08/08/11	6.20	6.10	6.30	6.30	6.15	0.15	0.15

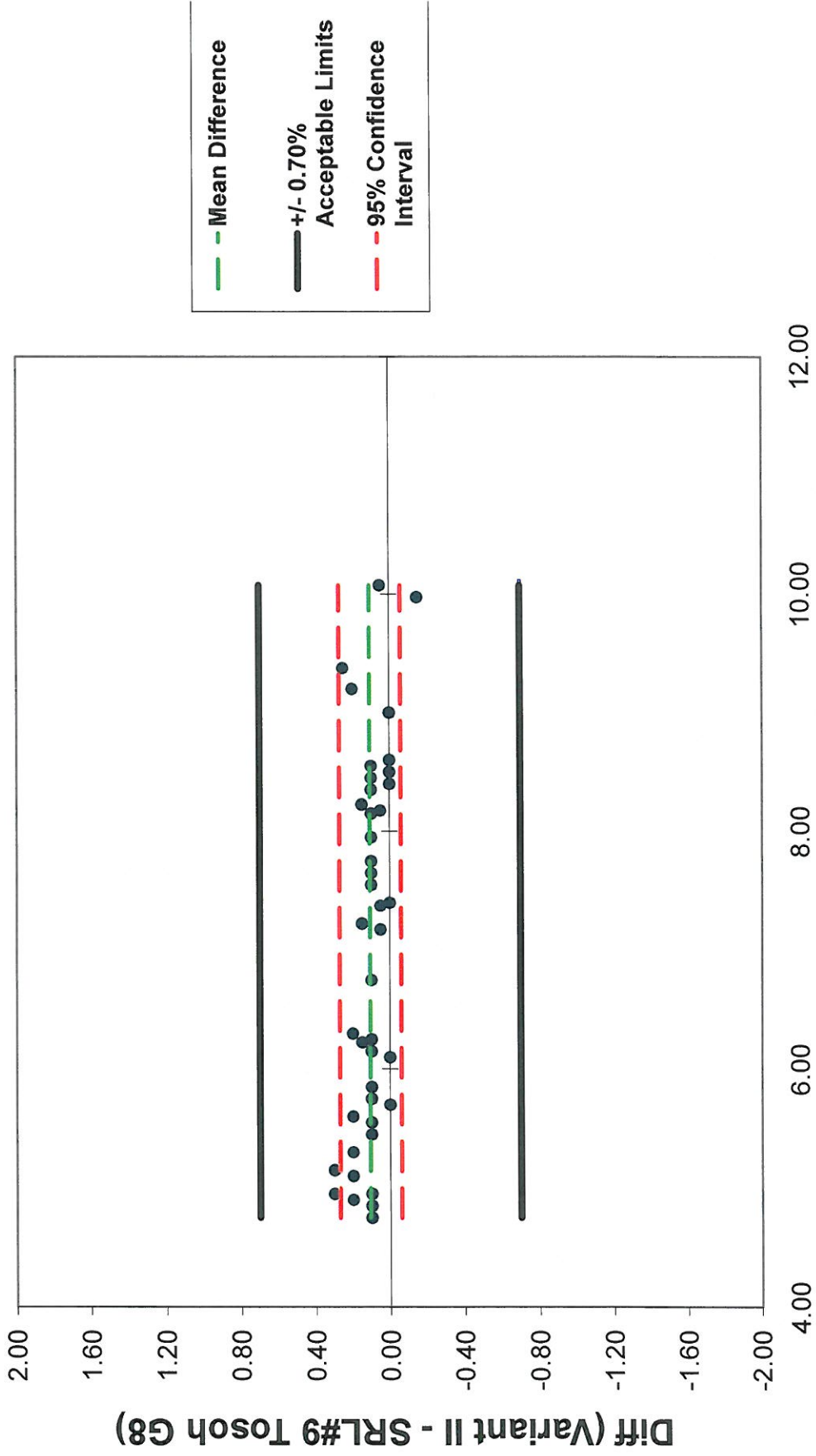
n=	80
Mean (Y-Mean X)	0.11
sd (Y-Mean X)	0.084

Confidence Interval	Acceptable		
Y- (Mean X)	Limit	Pass/Fail	
Lower 95%	-0.06	-0.70	Pass
Upper 95%	0.27	+0.70	Pass



# Level I Assessment of Agreement

Covance Central Laboratory (Shanghai)



Mean of SRL#9 Tosoh G8 and Variant II