

## NGSP Administrative Core

University of Missouri School of Medicine  
1 Hospital Drive M766 • Columbia, MO 65212 • (573) 882-1257 • Fax (573) 884-4748  
E-mail: [ngsp@missouri.edu](mailto:ngsp@missouri.edu) Web site: <http://www.ngsp.org>

November 8, 2019

Dr. Daniel Püntener  
Roche Diagnostics International Ltd  
Forrenstrasse 2  
CH-6343 Rotkreuz  
Switzerland

Dear Dr. Püntener,

Congratulations! We are pleased to inform you that Roche Diagnostics International Ltd has successfully completed the NGSP **Manufacturer** certification for the following method:

Instrument: <b>Cobas b 101</b>
Reagent Lot: <b>928131-01</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	# within 5%	Pass 36/40 Y/N
Cobas HbA1c Test on cobas b 101	40	Y

**Criteria for NGSP Manufacturer certification: 36/40 HbA1c results (single results) must be within  $\pm 5\%$  of the NGSP SRL mean (mean of duplicate results): Your method's results were within the NGSP criteria for Manufacturer Certification.**

**This certification is effective for one year and will expire on December 1, 2020. All data for next year's certification should be received by October 1, 2020.**

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 Report

<b>Location:</b>	Rotkreuz, Switzerland
<b>Manufacturer:</b>	Roche Diagnostics International Ltd
<b>Test Method (Y):</b>	cobas HbA1c Test on cobas b 101
<b>Comparative Method (X):</b>	SRL#9 G8
<b>Units of Measurement:</b>	% HbA1c
<b>Certification Type:</b>	Manufacturer

# Within 5%      40  
Pass 36          Yes

### Bias Estimation Data

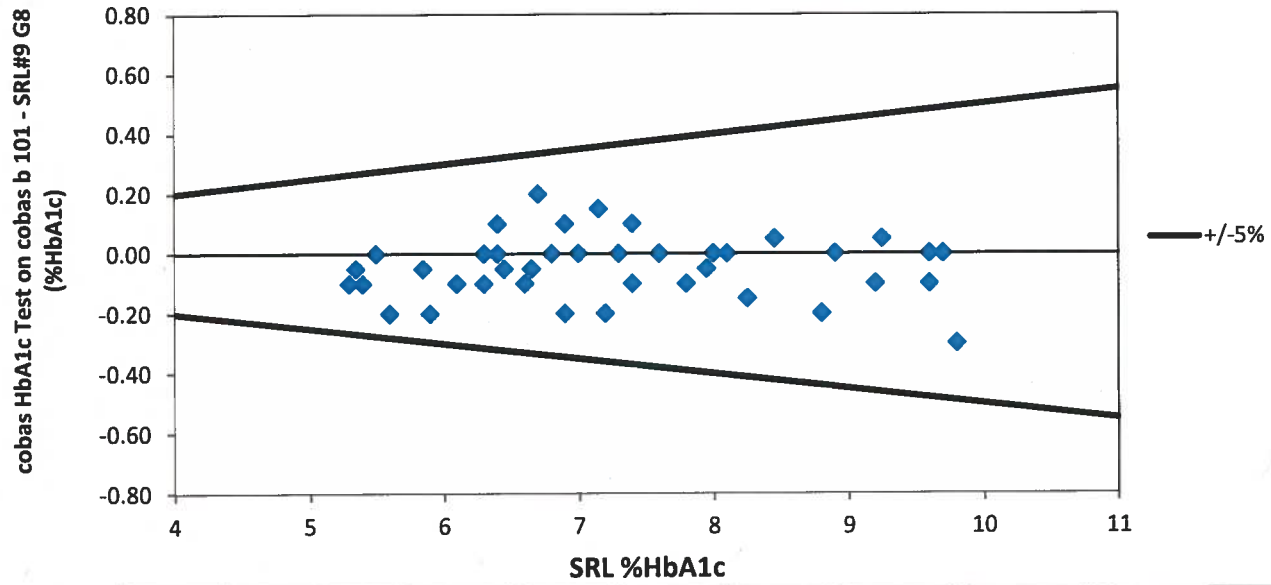
Test Method		0	Comparative Method	
Sample ID	Analysis Date	Y1	X1	X2
17087	10/28/2019	7.00	7.20	7.20
17088	10/28/2019	5.20	5.30	5.30
17089	10/28/2019	7.30	7.40	7.40
17090	10/28/2019	5.30	5.40	5.40
17091	10/28/2019	8.90	8.90	8.90
17092	10/28/2019	6.40	6.40	6.40
17093	10/28/2019	8.60	8.80	8.80
17094	10/28/2019	7.00	6.90	6.90
17095	10/29/2019	6.60	6.70	6.60
17096	10/29/2019	5.80	5.90	5.80
17097	10/29/2019	6.50	6.60	6.60
17098	10/29/2019	8.10	8.20	8.30
17099	10/29/2019	6.50	6.40	6.40
17100	10/29/2019	7.70	7.80	7.80
17101	10/29/2019	9.30	9.30	9.20
17102	10/29/2019	7.50	7.40	7.40
17103	10/30/2019	7.60	7.60	7.60
17104	10/30/2019	5.40	5.60	5.60
17105	10/30/2019	6.70	6.90	6.90
17106	10/30/2019	5.30	5.30	5.40
17107	10/30/2019	7.30	7.10	7.20
17108	10/30/2019	6.20	6.30	6.30
17109	10/30/2019	7.90	7.90	8.00
17110	10/30/2019	6.00	6.10	6.10
17111	10/31/2019	6.40	6.50	6.40
17112	10/31/2019	8.50	8.50	8.40
17113	10/31/2019	7.00	7.00	7.00
17114	10/31/2019	8.10	8.10	8.10
17115	10/31/2019	5.70	5.90	5.90
17116	10/31/2019	9.50	9.80	9.80
17117	10/31/2019	6.30	6.30	6.30
17118	10/31/2019	9.50	9.60	9.60
17119	11/01/2019	5.50	5.50	5.50
17120	11/01/2019	8.00	8.00	8.00
17121	11/01/2019	6.80	6.80	6.80
17122	11/01/2019	9.10	9.20	9.20
17123	11/01/2019	7.30	7.30	7.30
17124	11/01/2019	9.60	9.60	9.60
17125	11/01/2019	6.90	6.70	6.70
17126	11/01/2019	9.70	9.70	9.70

SRL Mean	Y	% Diff	Within 5%
7.20	7.00	-2.78%	Y
5.30	5.20	-1.89%	Y
7.40	7.30	-1.35%	Y
5.40	5.30	-1.85%	Y
8.90	8.90	0.00%	Y
6.40	6.40	0.00%	Y
8.80	8.60	-2.27%	Y
6.90	7.00	1.45%	Y
6.65	6.60	-0.75%	Y
5.85	5.80	-0.85%	Y
6.60	6.50	-1.52%	Y
8.25	8.10	-1.82%	Y
6.40	6.50	1.56%	Y
7.80	7.70	-1.28%	Y
9.25	9.30	0.54%	Y
7.40	7.50	1.35%	Y
7.60	7.60	0.00%	Y
5.60	5.40	-3.57%	Y
6.90	6.70	-2.90%	Y
5.35	5.30	-0.93%	Y
7.15	7.30	2.10%	Y
6.30	6.20	-1.59%	Y
7.95	7.90	-0.63%	Y
6.10	6.00	-1.64%	Y
6.45	6.40	-0.78%	Y
8.45	8.50	0.59%	Y
7.00	7.00	0.00%	Y
8.10	8.10	0.00%	Y
5.90	5.70	-3.39%	Y
9.80	9.50	-3.06%	Y
6.30	6.30	0.00%	Y
9.60	9.50	-1.04%	Y
5.50	5.50	0.00%	Y
8.00	8.00	0.00%	Y
6.80	6.80	0.00%	Y
9.20	9.10	-1.09%	Y
7.30	7.30	0.00%	Y
9.60	9.60	0.00%	Y
6.70	6.90	2.99%	Y
9.70	9.70	0.00%	Y



# Method Comparison Evaluation Report

## Bias Plot: cobas HbA1c Test on cobas b 101 vs. SRL#9 G8





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

**Manufacturer:** Roche Diagnostics International L Certification Type Manufacturer  
**Test Method (Y):** cobas HbA1c Test on cobas b 101  
**Comparative Method (X):** SRL#9 G8 **Report Date:** 11/07/19

Sample ID	Assay Date	Mean X	Y	Between Method Differences	Between Method
				Y-Mean X	Outliers
17087	10/28/19	7.20	7.00	-0.20	
17088	10/28/19	5.30	5.20	-0.10	
17089	10/28/19	7.40	7.30	-0.10	
17090	10/28/19	5.40	5.30	-0.10	
17091	10/28/19	8.90	8.90	0.00	
17092	10/28/19	6.40	6.40	0.00	
17093	10/28/19	8.80	8.60	-0.20	
17094	10/28/19	6.90	7.00	0.10	
17095	10/29/19	6.65	6.60	-0.05	
17096	10/29/19	5.85	5.80	-0.05	
17097	10/29/19	6.60	6.50	-0.10	
17098	10/29/19	8.25	8.10	-0.15	
17099	10/29/19	6.40	6.50	0.10	
17100	10/29/19	7.80	7.70	-0.10	
17101	10/29/19	9.25	9.30	0.05	
17102	10/29/19	7.40	7.50	0.10	
17103	10/30/19	7.60	7.60	0.00	
17104	10/30/19	5.60	5.40	-0.20	
17105	10/30/19	6.90	6.70	-0.20	
17106	10/30/19	5.35	5.30	-0.05	
17107	10/30/19	7.15	7.30	0.15	
17108	10/30/19	6.30	6.20	-0.10	
17109	10/30/19	7.95	7.90	-0.05	
17110	10/30/19	6.10	6.00	-0.10	
17111	10/31/19	6.45	6.40	-0.05	
17112	10/31/19	8.45	8.50	0.05	
17113	10/31/19	7.00	7.00	0.00	
17114	10/31/19	8.10	8.10	0.00	
17115	10/31/19	5.90	5.70	-0.20	
17116	10/31/19	9.80	9.50	-0.30	
17117	10/31/19	6.30	6.30	0.00	
17118	10/31/19	9.60	9.50	-0.10	
17119	11/01/19	5.50	5.50	0.00	
17120	11/01/19	8.00	8.00	0.00	
17121	11/01/19	6.80	6.80	0.00	
17122	11/01/19	9.20	9.10	-0.10	
17123	11/01/19	7.30	7.30	0.00	
17124	11/01/19	9.60	9.60	0.00	
17125	11/01/19	6.70	6.90	0.20	
17126	11/01/19	9.70	9.70	0.00	

	n=	Mean	sd	3sd	Upper Limit	Lower Limit	Outliers
Between Method	40	-0.046	0.105	0.314	0.268	-0.360	0

**Explanation:**  
 Between-method outliers exceed the mean +/- 3sd of the differences between methods.



# Scatter Plot

uche Diagnostics International Ltd cobas HbA1c Test on cobas b 101

% HbA1c (cobas HbA1c Test on cobas b 101)

