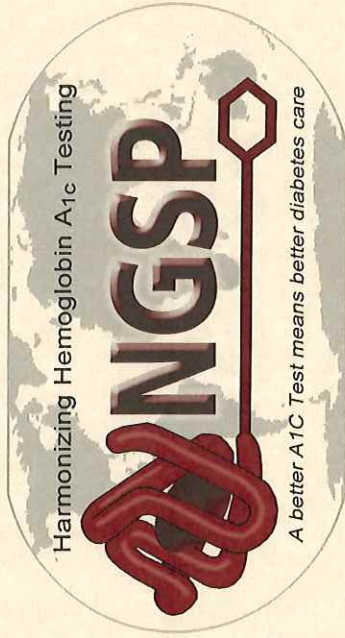




Certificate of Traceability

Level I Laboratory Certification

This certifies that **Eurofins Central Laboratory**, 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#12**

The system evaluated was:

Instrument: Variant II	Calibrator Lot: 6456844, 64566845	Column Lot: NU00061H
Reagent Lot: 64580496, 64581974, 64581975, 64581521	Calibrator Assigned Values: 5.4%, 10.5%	

Date of Certification: June 1, 2025

Certification Expires: June 1, 2026

Daniel South

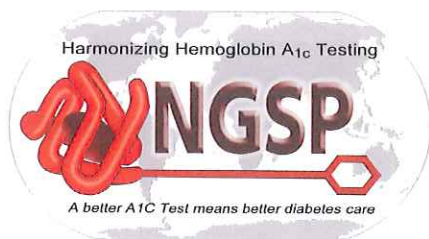
NGSP Steering Committee Chair

Randee R Little PhD.

NGSP Network Coordinator

Sharon Amalfi

SRL director/ supervisor



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 Web site: <http://www.ngsp.org>

April 17, 2025

Tom de Kerf
Eurofins Central Laboratory
Bergschot 71
4817 PA Breda
The Netherlands

Dear Dr. de Kerf,

Congratulations! We are pleased to inform you that Eurofins Central Laboratory has successfully completed the NGSP **Level I Laboratory** certification for the following method:

Instrument: Variant II	Calibrator Lot: 6456844, 64566845	Column Lot: NU00061H
Reagent Lot: 64580496, 64581974, 64581975, 64581521	Calibrator Assigned Values: 5.4%, 10.5%	

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 37/40 Y/N
Eurofins Central Laboratory, Breda, The Netherlands, VII	40	Y

Criteria for NGSP Level I certification: 37/40 HbA_{1c} 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 Level I Laboratory Certification.**

This certification is effective for one year and will expire on June 1, 2026. All data for next year's certification should be received by April 1, 2026. Your next set of quarterly monitoring samples is tentatively scheduled for June.

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

Sincerely,

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



Method Comparison Evaluation Report

Location:	Indianapolis, IN
Manufacturer:	Labcorp Central Laboratory Services, LP, US
Test Method (Y):	Variant II Turbo 2.0
Comparative Method (X):	SRL#12 D-100
Units of Measurement:	% HbA1c
Certification Type:	Level I Laboratory

Within 5% 40
Pass 37 Yes

Bias Estimation Data

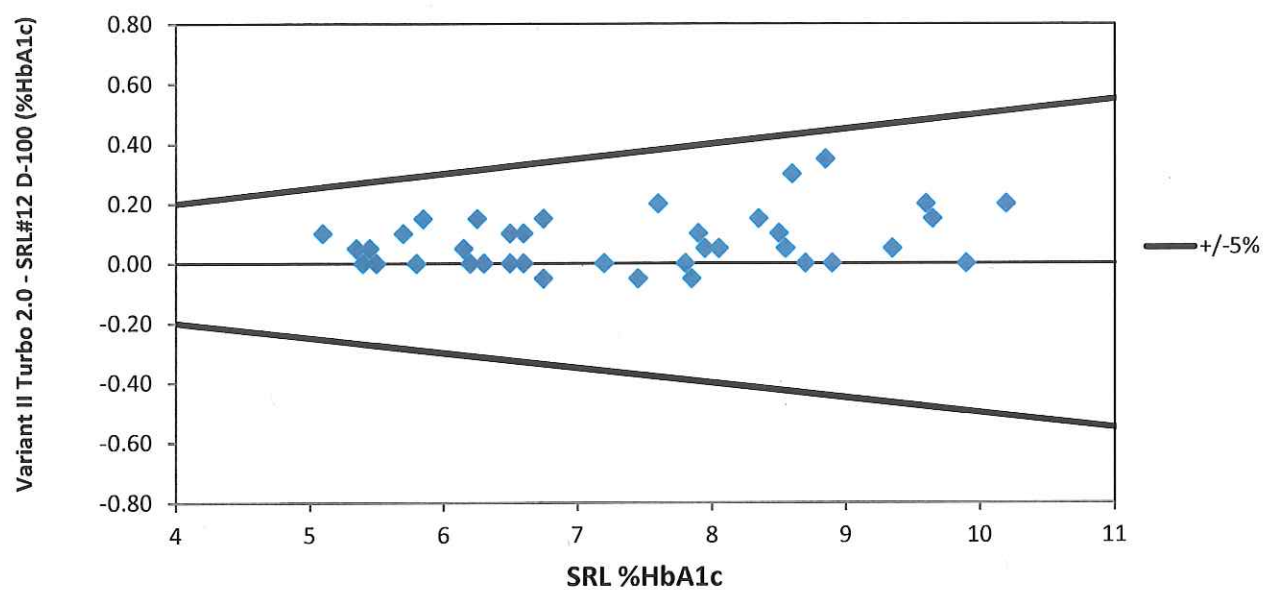
Test Method		0	Comparative Method	
Sample ID	Analysis Date	Y1	X1	X2
22847	04/08/2025	9.90	10.00	9.80
22848	04/08/2025	5.40	5.40	5.40
22849	04/08/2025	6.60	6.50	6.50
22850	04/08/2025	8.00	8.00	7.90
22851	04/08/2025	6.20	6.10	6.20
22852	04/08/2025	7.20	7.20	7.20
22853	04/08/2025	5.80	5.80	5.80
22854	04/08/2025	8.90	8.90	8.90
22855	04/09/2025	6.70	6.60	6.60
22856	04/09/2025	5.50	5.50	5.50
22857	04/09/2025	8.10	8.00	8.10
22858	04/09/2025	6.30	6.30	6.30
22859	04/09/2025	8.70	8.70	8.70
22860	04/09/2025	7.80	7.90	7.80
22861	04/09/2025	6.20	6.20	6.20
22862	04/09/2025	9.40	9.30	9.40
22863	04/10/2025	7.40	7.50	7.40
22864	04/10/2025	8.60	8.50	8.50
22865	04/10/2025	6.60	6.60	6.60
22866	04/10/2025	7.80	7.80	7.80
22867	04/10/2025	6.50	6.50	6.50
22868	04/10/2025	9.80	9.60	9.60
22869	04/10/2025	6.70	6.80	6.70
22870	04/10/2025	5.20	5.10	5.10
22871	04/15/2025	6.90	6.80	6.70
22872	04/15/2025	5.80	5.70	5.70
22873	04/15/2025	10.40	10.20	10.20
22874	04/15/2025	6.20	6.20	6.10
22875	04/15/2025	8.60	8.50	8.60
22876	04/15/2025	5.50	5.40	5.50
22877	04/15/2025	9.80	9.70	9.60
22878	04/15/2025	8.50	8.30	8.40
22879	04/16/2025	6.40	6.20	6.30
22880	04/16/2025	5.40	5.30	5.40
22881	04/16/2025	8.90	8.50	8.70
22882	04/16/2025	7.80	7.50	7.70
22883	04/16/2025	6.60	6.40	6.60
22884	04/16/2025	8.00	7.90	7.90
22885	04/16/2025	6.00	5.80	5.90
22886	04/16/2025	9.20	8.90	8.80

SRL Mean	Y	% Diff	Within 5%
9.90	9.90	0.00%	Y
5.40	5.40	0.00%	Y
6.50	6.60	1.54%	Y
7.95	8.00	0.63%	Y
6.15	6.20	0.81%	Y
7.20	7.20	0.00%	Y
5.80	5.80	0.00%	Y
8.90	8.90	0.00%	Y
6.60	6.70	1.52%	Y
5.50	5.50	0.00%	Y
8.05	8.10	0.62%	Y
6.30	6.30	0.00%	Y
8.70	8.70	0.00%	Y
7.85	7.80	-0.64%	Y
6.20	6.20	0.00%	Y
9.35	9.40	0.53%	Y
7.45	7.40	-0.67%	Y
8.50	8.60	1.18%	Y
6.60	6.60	0.00%	Y
7.80	7.80	0.00%	Y
6.50	6.50	0.00%	Y
9.60	9.80	2.08%	Y
6.75	6.70	-0.74%	Y
5.10	5.20	1.96%	Y
6.75	6.90	2.22%	Y
5.70	5.80	1.75%	Y
10.20	10.40	1.96%	Y
6.15	6.20	0.81%	Y
8.55	8.60	0.58%	Y
5.45	5.50	0.92%	Y
9.65	9.80	1.55%	Y
8.35	8.50	1.80%	Y
6.25	6.40	2.40%	Y
5.35	5.40	0.93%	Y
8.60	8.90	3.49%	Y
7.60	7.80	2.63%	Y
6.50	6.60	1.54%	Y
7.90	8.00	1.27%	Y
5.85	6.00	2.56%	Y
8.85	9.20	3.95%	Y



Method Comparison Evaluation Report

Bias Plot: Variant II Turbo 2.0 vs. SRL#12 D-100





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

Manufacturer: Labcorp Central Laboratory Service Certification Type Level I Laboratory
Test Method (Y): Variant II Turbo 2.0
Comparative Method (X): SRL#12 D-100 Report Date: 04/17/25

				Between Method Differences	Between Method Outliers
Sample ID	Assay Date	Mean X	Y	Y-Mean X	
22847	04/08/25	9.90	9.90	0.00	
22848	04/08/25	5.40	5.40	0.00	
22849	04/08/25	6.50	6.60	0.10	
22850	04/08/25	7.95	8.00	0.05	
22851	04/08/25	6.15	6.20	0.05	
22852	04/08/25	7.20	7.20	0.00	
22853	04/08/25	5.80	5.80	0.00	
22854	04/08/25	8.90	8.90	0.00	
22855	04/09/25	6.60	6.70	0.10	
22856	04/09/25	5.50	5.50	0.00	
22857	04/09/25	8.05	8.10	0.05	
22858	04/09/25	6.30	6.30	0.00	
22859	04/09/25	8.70	8.70	0.00	
22860	04/09/25	7.85	7.80	-0.05	
22861	04/09/25	6.20	6.20	0.00	
22862	04/09/25	9.35	9.40	0.05	
22863	04/10/25	7.45	7.40	-0.05	
22864	04/10/25	8.50	8.60	0.10	
22865	04/10/25	6.60	6.60	0.00	
22866	04/10/25	7.80	7.80	0.00	
22867	04/10/25	6.50	6.50	0.00	
22868	04/10/25	9.60	9.80	0.20	
22869	04/10/25	6.75	6.70	-0.05	
22870	04/10/25	5.10	5.20	0.10	
22871	04/15/25	6.75	6.90	0.15	
22872	04/15/25	5.70	5.80	0.10	
22873	04/15/25	10.20	10.40	0.20	
22874	04/15/25	6.15	6.20	0.05	
22875	04/15/25	8.55	8.60	0.05	
22876	04/15/25	5.45	5.50	0.05	
22877	04/15/25	9.65	9.80	0.15	
22878	04/15/25	8.35	8.50	0.15	
22879	04/16/25	6.25	6.40	0.15	
22880	04/16/25	5.35	5.40	0.05	
22881	04/16/25	8.60	8.90	0.30	
22882	04/16/25	7.60	7.80	0.20	
22883	04/16/25	6.50	6.60	0.10	
22884	04/16/25	7.90	8.00	0.10	
22885	04/16/25	5.85	6.00	0.15	
22886	04/16/25	8.85	9.20	0.35	Outlier

	n=	Mean	sd	3sd	Upper Limit	Lower Limit	Outliers
Between Method	40	0.074	0.091	0.274	0.348	-0.200	1

Explanation:

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



Scatter Plot

Abcorp Central Laboratory Services, LP, US Variant II Turbo 2.0

