

NGSP Administrative Core

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April 27, 2026

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: Bio-Rad Variant II	Calibrator Lot: 64662467, 64662469	Column Lot: CN00061
Reagent Lot: 64643969, 64664196, 64664197, 64594609	Calibrator Assigned Values: 5.6%, 10.2%	

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, Variant II	39	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, 2027. All data for next year's certification should be received by April 1, 2027. 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 ngsp.org.

Sincerely,

Curt Rohlfing,
NGSP Network Coordinator



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: Bio-Rad Variant II	Calibrator Lot: 64662467, 64662469	Column Lot: CN00061
Reagent Lot: 64643969, 64664196, 64664197, 64594609	Calibrator Assigned Values: 5.6%, 10.2%	

Date of Certification: June 1, 2026

Certification Expires: June 1, 2027

Daniel Searls

NGSP Steering Committee Chair

Christa Rollberg

NGSP Network Coordinator

[Signature]

SRL director/ supervisor



Method Comparison Evaluation Report--Data Entry

Location:	Breda, The Netherlands
Manufacturer:	Eurofins Central Laboratory
Test Method (Y):	Bio-Rad Variant II
Comparative Method (X):	SRL#12 D-100
Units of Measurement:	% HbA1c
Certification Type:	Level I Laboratory

Bias Estimation Data

Sample ID	Test Method		Comparative Method	
	Analysis Date	Y1	X1	X2
23847	09APR2026	9.50	9.3	9.3
23848	09APR2026	7.90	7.6	7.6
23849	09APR2026	9.80	9.8	9.8
23850	09APR2026	5.30	5.3	5.2
23851	09APR2026	6.10	6.0	6.0
23852	09APR2026	8.40	8.3	8.2
23853	09APR2026	6.50	6.4	6.4
23854	09APR2026	8.60	8.5	8.5
23855	10APR2026	5.20	5.4	5.3
23856	10APR2026	8.00	7.9	8.0
23857	10APR2026	6.40	6.2	6.2
23858	10APR2026	8.70	8.7	8.7
23859	10APR2026	6.10	6.2	6.1
23860	10APR2026	7.40	7.2	7.2
23861	10APR2026	10.30	9.9	9.8
23862	10APR2026	5.40	5.3	5.2
23863	13APR2026	8.20	8.2	8.0
23864	13APR2026	6.70	6.3	6.3
23865	13APR2026	7.70	7.6	7.6
23866	13APR2026	9.80	9.5	9.5
23867	13APR2026	6.40	6.3	6.2
23868	13APR2026	8.80	8.4	8.5
23869	13APR2026	5.40	5.4	5.4
23870	13APR2026	9.30	8.9	9.0
23871	14APR2026	7.30	7.2	7.2
23872	14APR2026	5.00	5.1	5.1
23873	14APR2026	5.90	6.0	5.9
23874	14APR2026	5.10	5.0	5.0
23875	14APR2026	7.10	7.1	6.9
23876	14APR2026	6.30	6.3	6.3
23877	14APR2026	9.80	9.8	9.8
23878	14APR2026	6.40	6.3	6.3
23879	15APR2026	5.80	5.9	5.8
23880	15APR2026	7.60	7.5	7.4
23881	15APR2026	6.20	6.1	6.1
23882	15APR2026	8.10	8.1	8.1
23883	15APR2026	6.50	6.3	6.3
23884	15APR2026	8.60	8.8	8.7
23885	15APR2026	5.90	6.0	5.9
23886	15APR2026	6.70	6.9	6.8

Regression Results

Slope: 1.033

Intercept: -0.142

r: 0.996

syc: 0.141

n: 40

5% Criterion

Within 5% 39

Pass 37 Yes



Method Comparison Evaluation Report

Location:	Breda, The Netherlands
Manufacturer:	Eurofins Central Laboratory
Test Method (Y):	Bio-Rad Variant II
Comparative Method (X):	SRL#12 D-100
Units of Measurement:	% HbA1c
Certification Type:	Level I Laboratory

Within 5% 39
Pass 37 Yes

Bias Estimation Data

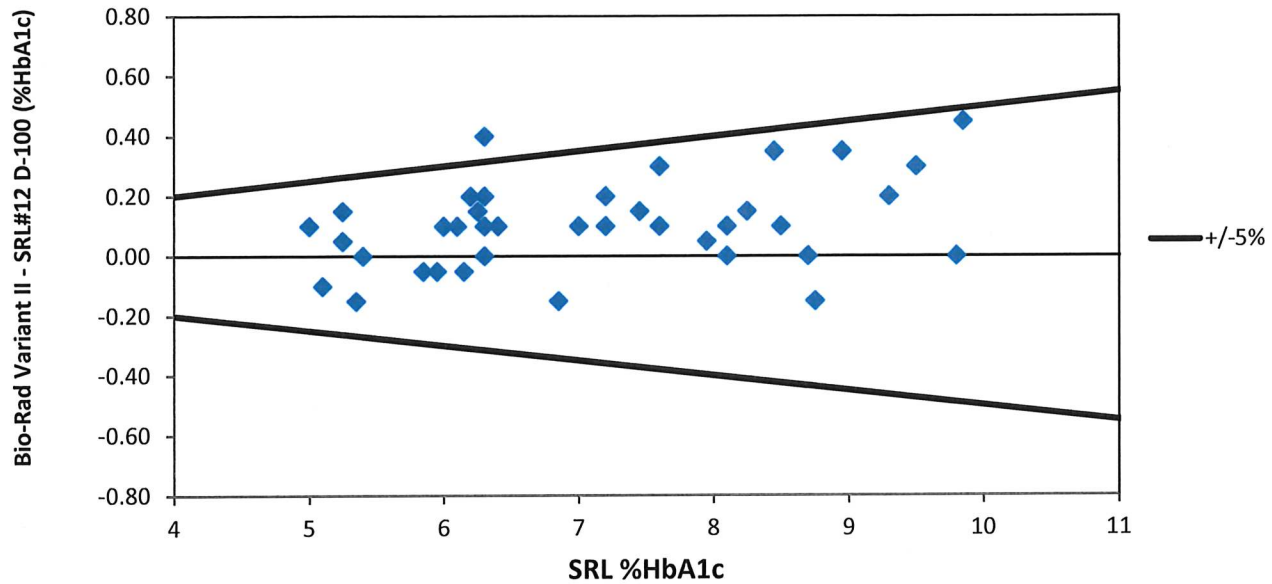
Test Method		0	Comparative Method	
Sample ID	Analysis Date	Y1	X1	X2
23847	09APR2026	9.50	9.30	9.30
23848	09APR2026	7.90	7.60	7.60
23849	09APR2026	9.80	9.80	9.80
23850	09APR2026	5.30	5.30	5.20
23851	09APR2026	6.10	6.00	6.00
23852	09APR2026	8.40	8.30	8.20
23853	09APR2026	6.50	6.40	6.40
23854	09APR2026	8.60	8.50	8.50
23855	10APR2026	5.20	5.40	5.30
23856	10APR2026	8.00	7.90	8.00
23857	10APR2026	6.40	6.20	6.20
23858	10APR2026	8.70	8.70	8.70
23859	10APR2026	6.10	6.20	6.10
23860	10APR2026	7.40	7.20	7.20
23861	10APR2026	10.30	9.90	9.80
23862	10APR2026	5.40	5.30	5.20
23863	13APR2026	8.20	8.20	8.00
23864	13APR2026	6.70	6.30	6.30
23865	13APR2026	7.70	7.60	7.60
23866	13APR2026	9.80	9.50	9.50
23867	13APR2026	6.40	6.30	6.20
23868	13APR2026	8.80	8.40	8.50
23869	13APR2026	5.40	5.40	5.40
23870	13APR2026	9.30	8.90	9.00
23871	14APR2026	7.30	7.20	7.20
23872	14APR2026	5.00	5.10	5.10
23873	14APR2026	5.90	6.00	5.90
23874	14APR2026	5.10	5.00	5.00
23875	14APR2026	7.10	7.10	6.90
23876	14APR2026	6.30	6.30	6.30
23877	14APR2026	9.80	9.80	9.80
23878	14APR2026	6.40	6.30	6.30
23879	15APR2026	5.80	5.90	5.80
23880	15APR2026	7.60	7.50	7.40
23881	15APR2026	6.20	6.10	6.10
23882	15APR2026	8.10	8.10	8.10
23883	15APR2026	6.50	6.30	6.30
23884	15APR2026	8.60	8.80	8.70
23885	15APR2026	5.90	6.00	5.90
23886	15APR2026	6.70	6.90	6.80

SRL Mean	Y	% Diff	Within 5%
9.30	9.50	2.15%	Y
7.60	7.90	3.95%	Y
9.80	9.80	0.00%	Y
5.25	5.30	0.95%	Y
6.00	6.10	1.67%	Y
8.25	8.40	1.82%	Y
6.40	6.50	1.56%	Y
8.50	8.60	1.18%	Y
5.35	5.20	-2.80%	Y
7.95	8.00	0.63%	Y
6.20	6.40	3.23%	Y
8.70	8.70	0.00%	Y
6.15	6.10	-0.81%	Y
7.20	7.40	2.78%	Y
9.85	10.30	4.57%	Y
5.25	5.40	2.86%	Y
8.10	8.20	1.23%	Y
6.30	6.70	6.35%	N
7.60	7.70	1.32%	Y
9.50	9.80	3.16%	Y
6.25	6.40	2.40%	Y
8.45	8.80	4.14%	Y
5.40	5.40	0.00%	Y
8.95	9.30	3.91%	Y
7.20	7.30	1.39%	Y
5.10	5.00	-1.96%	Y
5.95	5.90	-0.84%	Y
5.00	5.10	2.00%	Y
7.00	7.10	1.43%	Y
6.30	6.30	0.00%	Y
9.80	9.80	0.00%	Y
6.30	6.40	1.59%	Y
5.85	5.80	-0.85%	Y
7.45	7.60	2.01%	Y
6.10	6.20	1.64%	Y
8.10	8.10	0.00%	Y
6.30	6.50	3.17%	Y
8.75	8.60	-1.71%	Y
5.95	5.90	-0.84%	Y
6.85	6.70	-2.19%	Y



Method Comparison Evaluation Report

Bias Plot: Bio-Rad Variant II vs. SRL#12 D-100





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

Manufacturer: Eurofins Central Laboratory Certification Type: Level I Laboratory
 Test Method (Y): Bio-Rad Variant II
 Comparative Method (X): SRL#12 D-100 Report Date: 04/23/26

				Between Method Differences	Between Method Outliers
Sample ID	Assay Date	Mean X	Y	Y-Mean X	
23847	09APR2026	9.30	9.50	0.20	
23848	09APR2026	7.60	7.90	0.30	
23849	09APR2026	9.80	9.80	0.00	
23850	09APR2026	5.25	5.30	0.05	
23851	09APR2026	6.00	6.10	0.10	
23852	09APR2026	8.25	8.40	0.15	
23853	09APR2026	6.40	6.50	0.10	
23854	09APR2026	8.50	8.60	0.10	
23855	10APR2026	5.35	5.20	-0.15	
23856	10APR2026	7.95	8.00	0.05	
23857	10APR2026	6.20	6.40	0.20	
23858	10APR2026	8.70	8.70	0.00	
23859	10APR2026	6.15	6.10	-0.05	
23860	10APR2026	7.20	7.40	0.20	
23861	10APR2026	9.85	10.30	0.45	
23862	10APR2026	5.25	5.40	0.15	
23863	13APR2026	8.10	8.20	0.10	
23864	13APR2026	6.30	6.70	0.40	
23865	13APR2026	7.60	7.70	0.10	
23866	13APR2026	9.50	9.80	0.30	
23867	13APR2026	6.25	6.40	0.15	
23868	13APR2026	8.45	8.80	0.35	
23869	13APR2026	5.40	5.40	0.00	
23870	13APR2026	8.95	9.30	0.35	
23871	14APR2026	7.20	7.30	0.10	
23872	14APR2026	5.10	5.00	-0.10	
23873	14APR2026	5.95	5.90	-0.05	
23874	14APR2026	5.00	5.10	0.10	
23875	14APR2026	7.00	7.10	0.10	
23876	14APR2026	6.30	6.30	0.00	
23877	14APR2026	9.80	9.80	0.00	
23878	14APR2026	6.30	6.40	0.10	
23879	15APR2026	5.85	5.80	-0.05	
23880	15APR2026	7.45	7.60	0.15	
23881	15APR2026	6.10	6.20	0.10	
23882	15APR2026	8.10	8.10	0.00	
23883	15APR2026	6.30	6.50	0.20	
23884	15APR2026	8.75	8.60	-0.15	
23885	15APR2026	5.95	5.90	-0.05	
23886	15APR2026	6.85	6.70	-0.15	

	n=	Mean	sd	3sd	Upper Limit	Lower Limit	Outliers
Between Method	40	0.098	0.148	0.443	0.540	-0.345	0

Explanation:

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



Scatter Plot

Eurofins Central Laboratory Bio-Rad Variant II

