



Certificate of Traceability

Manufacturer Certification

This certifies that **iXensor Co., LTD.**, using **PixoTest POCT System** has participated in and successfully completed the NGSP certification for manufacturers and is traceable to the **Diabetes Control and Complications Trial Reference method**. The comparison was performed with: **Reference Material Institute for Clinical Chemistry Standards (ReCCS) ASRL#1**

The system evaluated was:

Instrument:	Application:
PixoTest POCT System	Spoit collection device
Reagent Lot:	
RDY17D01A, RDY17D01A	

Date of Certification: December 1, 2017

Certification Expires: December 1, 2018

Daniel Smith

NGSP Steering Committee Chair

Randee R Little PhD.

NGSP Network Coordinator

Viola G. Raneva M.D.

SRL director/ supervisor

ReCCS
Reference Material Institute for Clinical Chemistry Standards

December 15, 2017

Polly Lai
iXensor Co., LTD.
6F., No.9, Aly. 2, Ln. 35, Jihu Rd., Neihu Dist.,
Taipei City 114, Taiwan (R.O.C.)

Dear Dr. Polly Lai,

Congratulations! Your laboratory has succeeded in the NGSP certification and the
Certificates are enclosed.

Sincerely yours,

Name : *Hirohito Umemoto*
Hirohito Umemoto Ph.D.

Title : President

Institute : Reference Material Institute for Clinical Chemistry Standards(ReCCS)
(NGSP ASRL#1)

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NGSP Administrative Core

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November 29, 2017

Polly Lai
iXensor Co., LTD.
6F., No.9, Aly. 2, Ln. 35, Jihu Rd., Neihu Dist.,
Taipei City 114, Taiwan (R.O.C.)

Dear Dr. Lai,

Congratulations! We are pleased to inform you that iXensor Co., LTD. has successfully completed the NGSP **Manufacturer** certification for the following methods:

Instrument: PixoTest POCT System	Application: Spoit collection device
Reagent Lot: RDY17D01A, RDY17D01A	

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 6%	Pass 37/40 Y/N
PixoTest POCT System	40	Y

Criteria for NGSP Manufacturer certification: 37/40 HbA1c results (single results) must be within $\pm 6\%$ 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, 2018. All data for next year's certification should be received by October 2018.

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:	Taipei City, Taiwan		
Manufacturer:	iXensor Co., Ltd.		
Test Method (Y):	PixoTest POCT System	# Within 6%	40
Comparative Method (X):	ASRL#1 KO-500	Pass 37	Yes
Units of Measurement:	% HbA1c		
Certification Type:	Manufacturer		

Bias Estimation Data

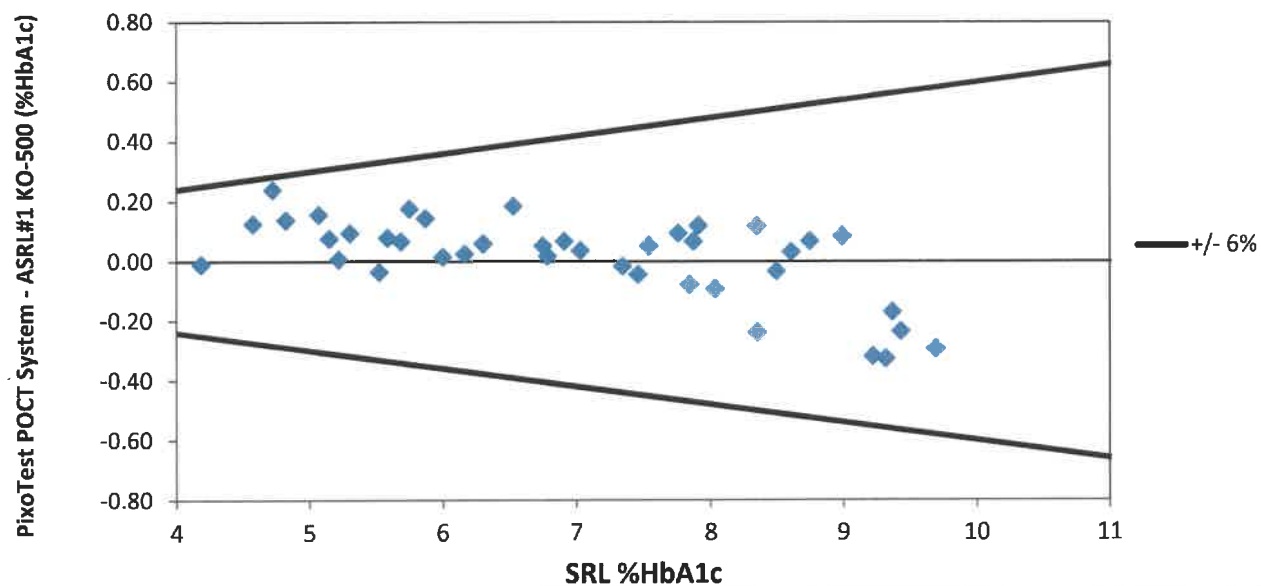
Test Method		0	Comparative Method	
Sample ID	Analysis Date	Y1	X1	X2
No.1	10/02/2017	4.96	4.70	4.75
No.2	10/02/2017	4.18	4.17	4.20
No.4	10/02/2017	4.96	4.82	4.83
No.5	10/02/2017	5.40	5.28	5.33
No.6	10/02/2017	5.49	5.51	5.54
No.7	10/02/2017	5.93	5.76	5.74
No.8	10/02/2017	6.01	5.85	5.89
No.9	10/03/2017	6.01	6.00	6.00
No.11	10/03/2017	6.37	6.30	6.31
No.13	10/03/2017	6.72	6.53	6.53
No.14	10/03/2017	7.77	7.84	7.85
No.15	10/03/2017	6.80	6.76	6.81
No.16	10/03/2017	7.85	7.76	7.76
No.17	10/04/2017	6.80	6.73	6.77
No.18	10/04/2017	6.98	6.90	6.92
No.20	10/04/2017	7.33	7.32	7.37
No.23	10/04/2017	9.08	8.93	9.06
No.24	10/04/2017	8.47	8.51	8.49
No.25	10/05/2017	8.64	8.59	8.63
No.27	10/05/2017	8.03	7.91	7.91
No.28	10/05/2017	7.94	8.02	8.05
No.29	10/05/2017	5.23	5.11	5.19
No.30	10/05/2017	4.70	4.59	4.56
No.32	10/05/2017	5.23	5.22	5.22
No.34	10/06/2017	5.23	5.08	5.06
No.35	10/06/2017	6.19	6.16	6.17
No.36	10/06/2017	5.66	5.56	5.61
No.39	10/06/2017	5.75	5.68	5.69
No.41	10/11/2017	7.42	7.47	7.45
No.42	10/11/2017	7.59	7.56	7.52
No.43	10/11/2017	7.07	7.00	7.06
No.44	10/11/2017	7.94	7.86	7.89
No.45	10/11/2017	8.82	8.75	8.75
No.46	10/11/2017	8.12	8.35	8.36
No.47	10/11/2017	8.47	8.35	8.35
No.3	11/27/2017	9.20	9.36	9.38
No.4	11/27/2017	8.91	9.19	9.26
No.5	11/27/2017	8.99	9.29	9.35
No.6	11/27/2017	9.20	9.41	9.46
No.8	11/27/2017	9.40	9.68	9.71

SRL Mean	Y	% Diff	Within 6%
4.73	4.96	5.05%	Y
4.19	4.18	-0.23%	Y
4.83	4.96	2.87%	Y
5.31	5.40	1.79%	Y
5.53	5.49	-0.65%	Y
5.75	5.93	3.08%	Y
5.87	6.01	2.47%	Y
6.00	6.01	0.25%	Y
6.31	6.37	0.96%	Y
6.53	6.72	2.84%	Y
7.85	7.77	-1.00%	Y
6.79	6.80	0.27%	Y
7.76	7.85	1.22%	Y
6.75	6.80	0.79%	Y
6.91	6.98	0.99%	Y
7.35	7.33	-0.22%	Y
9.00	9.08	0.95%	Y
8.50	8.47	-0.38%	Y
8.61	8.64	0.38%	Y
7.91	8.03	1.51%	Y
8.04	7.94	-1.16%	Y
5.15	5.23	1.49%	Y
4.58	4.70	2.75%	Y
5.22	5.23	0.12%	Y
5.07	5.23	3.09%	Y
6.17	6.19	0.41%	Y
5.59	5.66	1.42%	Y
5.69	5.75	1.18%	Y
7.46	7.42	-0.58%	Y
7.54	7.59	0.68%	Y
7.03	7.07	0.51%	Y
7.88	7.94	0.85%	Y
8.75	8.82	0.78%	Y
8.36	8.12	-2.85%	Y
8.35	8.47	1.41%	Y
9.37	9.20	-1.81%	Y
9.23	8.91	-3.46%	Y
9.32	8.99	-3.51%	Y
9.44	9.20	-2.49%	Y
9.70	9.40	-3.04%	Y



Method Comparison Evaluation Report

Bias Plot: PixoTest POCT System vs. ASRL#1 KO-500





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

Manufacturer:	iXensor Co., Ltd.	Certification Type: Manufacturer
Test Method (Y):	PixoTest POCT System	
Comparative Method (X):	ASRL#1 KO-500	Report Date: 11/29/17

				Between Method Differences	Between Method Outliers
Sample ID	Assay Date	Mean X	Y	Y-Mean X	
No.1	10/02/17	4.73	4.96	0.24	
No.2	10/02/17	4.19	4.18	-0.01	
No.4	10/02/17	4.83	4.96	0.14	
No.5	10/02/17	5.31	5.40	0.10	
No.6	10/02/17	5.53	5.49	-0.04	
No.7	10/02/17	5.75	5.93	0.18	
No.8	10/02/17	5.87	6.01	0.14	
No.9	10/03/17	6.00	6.01	0.01	
No.11	10/03/17	6.31	6.37	0.06	
No.13	10/03/17	6.53	6.72	0.19	
No.14	10/03/17	7.85	7.77	-0.08	
No.15	10/03/17	6.79	6.80	0.02	
No.16	10/03/17	7.76	7.85	0.09	
No.17	10/04/17	6.75	6.80	0.05	
No.18	10/04/17	6.91	6.98	0.07	
No.20	10/04/17	7.35	7.33	-0.02	
No.23	10/04/17	9.00	9.08	0.09	
No.24	10/04/17	8.50	8.47	-0.03	
No.25	10/05/17	8.61	8.64	0.03	
No.27	10/05/17	7.91	8.03	0.12	
No.28	10/05/17	8.04	7.94	-0.09	
No.29	10/05/17	5.15	5.23	0.08	
No.30	10/05/17	4.58	4.70	0.13	
No.32	10/05/17	5.22	5.23	0.01	
No.34	10/06/17	5.07	5.23	0.16	
No.35	10/06/17	6.17	6.19	0.03	
No.36	10/06/17	5.59	5.66	0.08	
No.39	10/06/17	5.69	5.75	0.07	
No.41	10/11/17	7.46	7.42	-0.04	
No.42	10/11/17	7.54	7.59	0.05	
No.43	10/11/17	7.03	7.07	0.04	
No.44	10/11/17	7.88	7.94	0.07	
No.45	10/11/17	8.75	8.82	0.07	
No.46	10/11/17	8.36	8.12	-0.24	
No.47	10/11/17	8.35	8.47	0.12	
No.3	11/27/17	9.37	9.20	-0.17	
No.4	11/27/17	9.23	8.91	-0.32	
No.5	11/27/17	9.32	8.99	-0.33	
No.6	11/27/17	9.44	9.20	-0.24	
No.8	11/27/17	9.70	9.40	-0.30	

	n=	Mean	sd	3sd	Upper Limit	Lower Limit	Outliers
Between Method	40	0.013	0.139	0.416	0.429	-0.403	0

Explanation:

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



Scatter Plot

iXensor Co., Ltd. PixoTest POCT System

