

	Meter Certificate of Conformance	Date Released 17 Nov 2017
	Confidential: This is a controlled document, no copy or printing is permitted without the authorized approval.	Revision Level 2

CareSens N Meter Certificate of Conformance

Customer: Norma
i-SENS Product Code: 256333-201
Production Lot: A501083K
Meter Serial No.: A501083K0001 ~ A501083K1000
Shipping Quantity (ea.): 1,000
C of C No.: QCMSNA385

1. Appearance Inspection

Inspection Item	Result
Packaging Box	PASS
Meter(including LCD)	PASS

2. Performance Test

Test Item	Results
Button Operation	PASS
Sensor Measurement Operation	PASS
Simulator Sensitivity	N/A
Control Solution Sensitivity	PASS
Recognition of no code pattern	PASS

THE ABOVE REFERENCED MATERIAL HAS BEEN APPROVED AND RELEASED BY i-SENS.

i-SENS QA or designee: Youn Jung Chang Date: 2021.04.22

i-sens	Test Strip Certificate of Conformance	Date Released 11.Oct.2017
	Confidential : This is a controlled document, no copy or printing is permitted without the authorized approval.	Revision Level 6

CareSens N Test Strip Certificate of Conformance

i-SENS Product Code: 256333-201
Lot No.: TM08LW79F
Calibration Code: -
Manufacture Date: 2021/04/08
Expiration Date: 2023/04
QC Tested Quantity (strips): 240
C of C No.: QCSA005856

Test 1. Measurement with Blood*

	Average	Standard Deviation
Slope	0.9544	0.0093
y-intercept	-29.2213	1.3522

*Range: 70 mg/dL ~ 400 mg/dL

Test 2. Measurement with Blood

YSI value(mg/dL)	Standard Deviation	CV%	
		A.C.**	Result
130	3.1	≤ 5.0	3.4
195	4.1	≤ 5.0	2.7
301	10.4	≤ 5.0	4.0

**A.C.: acceptance criteria

Test 3. Measurement with Control Solution

Control	CV%	Average (mg/dL)	Min. (mg/dL)	Max. (mg/dL)	Range
A	3.0	136.1	127	146	116~156 mg/dL 6.4~8.7 mmol/L
B	2.4	245.0	236	262	208~282 mg/dL 11.6~15.7 mmol/L

**THE ABOVE REFERENCED MATERIAL HAS BEEN
APPROVED AND RELEASED BY i-SENS.**

Originated by: Chul Seon Lee Date: 2021. 04. 22

Approved by: Chul Hee Han Date: 2021. 04. 22

i-sens	Test Strip Certificate of Conformance	Date Released 11.Oct.2017
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CareSens N Test Strip Certificate of Conformance

i-SENS Product Code: 256104-201
Lot No.: TM03LW69E
Calibration Code: -
Manufacture Date: 2021/04/03
Expiration Date: 2023/04
QC Tested Quantity (strips): 240
C of C No.: QCSA005857

Test 1. Measurement with Blood*

	Average	Standard Deviation
Slope	1.0352	0.0138
y-intercept	-39.9534	2.7864

*Range: 70 mg/dL ~ 400 mg/dL

Test 2. Measurement with Blood

YSI value(mg/dL)	Standard Deviation	CV%	
		A.C.**	Result
125	2.2	≤ 5.0	2.6
202	3.8	≤ 5.0	2.3
299	5.9	≤ 5.0	2.2

**A.C.: acceptance criteria

Test 3. Measurement with Control Solution

Control	CV%	Average (mg/dL)	Min. (mg/dL)	Max. (mg/dL)	Range
A	2.3	134.6	129	141	114~155 mg/dL 6.4~8.6 mmol/L
B	2.1	242.9	230	252	206~279 mg/dL 11.5~15.5 mmol/L

**THE ABOVE REFERENCED MATERIAL HAS BEEN
APPROVED AND RELEASED BY i-SENS.**

Originated by: Chul Fra Lee Date: 2021. 09. 22

Approved by: Chul Hee Han Date: 2021. 09. 22

i-sens	Test Strip Certificate of Conformance	Date Released 11.Oct.2017
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CareSens N Test Strip Certificate of Conformance

i-SENS Product Code: 256104-201
Lot No.: TM09LW81B
Calibration Code: -
Manufacture Date: 2021/04/09
Expiration Date: 2023/04
QC Tested Quantity (strips): 240
C of C No.: QCSA005858

Test 1. Measurement with Blood*

	Average	Standard Deviation
Slope	0.9730	0.0166
y-intercept	-26.3611	3.0764

*Range: 70 mg/dL ~ 400 mg/dL

Test 2. Measurement with Blood

YSI value(mg/dL)	Standard Deviation	CV%	
		A.C.**	Result
130	3.1	≤ 5.0	3.2
195	4.6	≤ 5.0	2.9
301	7.9	≤ 5.0	3.0

**A.C.: acceptance criteria

Test 3. Measurement with Control Solution

Control	CV%	Average (mg/dL)	Min. (mg/dL)	Max. (mg/dL)	Range
A	2.8	135.5	127	143	115~156 mg/dL 6.4~8.7 mmol/L
B	2.1	238.9	224	250	203~275 mg/dL 11.3~15.3 mmol/L

THE ABOVE REFERENCED MATERIAL HAS BEEN APPROVED AND RELEASED BY i-SENS.

Originated by: Chul Jim Lee Date: 2021.04.22

Approved by: Chul Hee Han Date: 2021.04.22