

	<b>Meter Certificate of Conformance</b>	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**

<b>Customer: Norma</b>
<b>i-SENS Product Code: 256333-201</b>
<b>Production Lot: A501333J</b>
<b>Meter Serial No.: A501333J0001 ~ A501333J1000</b>
<b>Shipping Quantity (ea.): 1,000</b>
<b>C of C No.: QCMSNA377</b>

**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: 2020.12.28

<b>i-sens</b>	<b>Test Strip Certificate of Conformance</b>	Date Released 11.Oct.2017
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**CareSens N Test Strip Certificate of Conformance**

<b>i-SENS Product Code: 256104-201</b>
<b>Lot No.: SS01LR36B</b>
<b>Calibration Code: -</b>
<b>Manufacture Date: 2020/10/01</b>
<b>Expiration Date: 2022/09</b>
<b>QC Tested Quantity (strips): 240</b>
<b>C of C No.: QCSA004837</b>

**Test 1. Measurement with Blood\***

	<b>Average</b>	<b>Standard Deviation</b>
<b>Slope</b>	1.0024	0.0271
<b>y-intercept</b>	-24.4702	3.7280

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

**Test 2. Measurement with Blood**

YSI value(mg/dL)	Standard Deviation	CV%	
		A.C.**	Result
128	3.2	≤ 5.0	3.2
199	5.6	≤ 5.0	3.4
297	8.4	≤ 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	2.6	136.9	131	147	116~157 mg/dL 6.5~8.7 mmol/L
B	2.8	238.6	224	256	203~274 mg/dL 11.3~15.2 mmol/L

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

Originated by: Chul Jun Lee Date: 2020.12.03

Approved by: Chul Hee Han Date: 2020.12.03

<b>i-sens</b>	<b>Test Strip Certificate of Conformance</b>	Date Released 11.Oct.2017
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**CareSens N Test Strip Certificate of Conformance**

<b>i-SENS Product Code: 256104-201</b>
<b>Lot No.: SB15LS09A</b>
<b>Calibration Code: -</b>
<b>Manufacture Date: 2020/11/15</b>
<b>Expiration Date: 2022/11</b>
<b>QC Tested Quantity (strips): 240</b>
<b>C of C No.: QCSA004838</b>

**Test 1. Measurement with Blood\***

	<b>Average</b>	<b>Standard Deviation</b>
<b>Slope</b>	0.9439	0.0269
<b>y-intercept</b>	-23.1083	2.8862

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

**Test 2. Measurement with Blood**

YSI value(mg/dL)	Standard Deviation	CV%	
		A.C.**	Result
135	3.8	≤ 5.0	3.6
203	6.7	≤ 5.0	4.0
304	8.3	≤ 5.0	3.2

\*\*A.C.: acceptance criteria

**Test 3. Measurement with Control Solution**

Control	CV%	Average (mg/dL)	Min. (mg/dL)	Max. (mg/dL)	Range
A	2.7	132.6	127	141	113~153 mg/dL 6.3~8.5 mmol/L
B	2.5	232.6	224	252	198~268 mg/dL 11.0~14.9 mmol/L

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

Originated by: Chul Jia Lee Date: 2020.12.03

Approved by: Chul Hee Han Date: 2020.12.03

<b>i-sens</b>	<b>Test Strip Certificate of Conformance</b>	Date Released 11.Oct.2017
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**CareSens N Test Strip Certificate of Conformance**

<b>i-SENS Product Code: 256333-201</b>
<b>Lot No.: SN05LS48A</b>
<b>Calibration Code: -</b>
<b>Manufacture Date: 2020/12/05</b>
<b>Expiration Date: 2022/12</b>
<b>QC Tested Quantity (strips): 240</b>
<b>C of C No.: QCSA005028</b>

**Test 1. Measurement with Blood\***

	<b>Average</b>	<b>Standard Deviation</b>
<b>Slope</b>	0.9363	0.0093
<b>y-intercept</b>	-21.4118	2.2451

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

**Test 2. Measurement with Blood**

YSI value(mg/dL)	Standard Deviation	CV%	
		A.C.**	Result
125	3.4	≤ 5.0	3.8
203	5.9	≤ 5.0	3.4
305	8.1	≤ 5.0	3.1

\*\*A.C.: acceptance criteria

**Test 3. Measurement with Control Solution**

Control	CV%	Average (mg/dL)	Min. (mg/dL)	Max. (mg/dL)	Range
A	2.5	141.6	134	152	120~163 mg/dL 6.7~9.0 mmol/L
B	2.0	249.3	239	258	212~287 mg/dL 11.8~15.9 mmol/L

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

Originated by: Chul Sa Lee

Date : 2020.12.28

Approved by: Chul Hee Han

Date : 2020.12.28