InSight Keto Vet
Precision Evaluation Report

Repeatability Evaluation

Scope and Objective

The objective of this study was to evaluate the repeatability of the InSight Keto Vet Meter.

The repeatability study was performed using cattle venous whole blood samples which were pre-adjusted into four different ketone concentrations. Each concentration was studied using 10 different meters and each meter performed 10 tests. The reference value was determined by the HITACHI 704 Automatic Analyser.

The meters were checked according to the user guide before each test to make sure that they were in normal working condition. The HITACHI 704 Automatic Analyser was calibrated prior to each test using the standard reference RANDOX assay kit.

Materials

- 10 InSight Keto Vet Meters: SN eB-K04RD01~10
- 3 Lots of InSight Keto Vet Test Strips, 40 Vials Per Lot (10 Test Strips/Vial): Lot No. LK02RD01~3
- Code Card
- HITACHI 704 Automatic Analyser: SN 6338015
- Standard Reference: RANDOX Assay Kit (RB1007)

Test Protocol

Sample Preparation: Venous whole blood samples (haematocrit value of 30%~60%) are adjusted into the following ketone concentrations:

- 0.4~0.6 mmol/L
- 1.0~1.4 mmol/L
- 2.2~2.6 mmol/L
- 5.7~6.3 mmol/L

1. Use a calibrated reference to determine the blood ketone level of all samples.
2. Meters should be checked according to the user guide to make sure that the meters are in normal working condition.
3. The test conditions should be:
   - Temperature: 23°C±2°C
   - Humidity: 30%~85%
   - Check conditions before each test and every hour during test. If conditions are within specification, continue testing. If test conditions are not within the specification, stop testing and repeat all tests since last approved condition check.
   - Steps 4-14 should be carried out using two people, one person is responsible for the operation of all the test steps and the other one is responsible for recording the test results.
4. For each test, time and ketone readings should be recorded. All data should be written correctly and should

be easily distinguished between the association of the readings and the meters.
5. After each test, remove and discard the test strip.
6. Repeatability Evaluation: This repeatability evaluation consists of four tests according to the four different ketone levels. Each concentration was studied using 10 different meters and each meter performed 10 tests.
7. Obtain the required materials and equipment.
8. Record the serial numbers of the InSight Keto Vet Meters and the Lot No. of each vial of InSight Keto Vet Test Strips.
9. Each level of sample was confirmed by the HITACHI 704 Automatic Analyser with the RANDOX Assay Kit (RB1007) two times and the equivalent digital reading was recorded.
10. Insert the InSight Keto Vet Test Strip into the meter. Apply a drop of the venous whole blood sample, with a ketone concentration adjusted within the range of 0.4~0.6 mmol/L, on the test zone of the test strip and wait for the test result. Repeat this experiment 10 times for each meter.
11. Repeat step 10 for the other three blood samples with ketone concentration of 1.0~1.4, 2.2~2.6 and 5.7~6.3 mmol/L, respectively.
12. Repeat steps 10-11 for the other two lots of the test strips.
13. Documentation Review: Review data recordings for data completeness and accuracy.

Acceptance Criteria

The results of this repeatability evaluation were analysed:
Blood Ketone Concentration: <1.5 mmol/L, SD*<0.15 mmol/L
Blood Ketone Concentration ≥1.5 mmol/L, CV*<6%

*Coefficient of Variation (CV)
*Standard Deviation (SD)

Test Results

Readings of the three lots of InSight Keto Vet Test Strips were recorded and analysed separately. The results of repeatability analysis are shown in Exhibit 1. The precision evaluation for each of the three lots of test strips in four ketone concentrations is generally:

1. For ketone concentrations <1.5 mmol/L: Standard Deviation (SD) for the readings of each meter is <0.15 mmol/L.
2. For ketone concentrations ≥1.5 mmol/L: Coefficient of Variation (CV) for the readings of each meter within a range of 6%.

Average (AVG), Standard Deviation (SD), and Coefficient of Variation (CV) for Each Combination of Ketone Concentration and Strip Lot

Unit: mmol/L

Strip Lot. HITACHI	0.52	1.19	2.55	6.13
LK02RD01	0.5	1.1	2.5	6.0
LK02RD02	0.5	1.1	2.5	6.0
LK02RD03	0.5	1.0	2.6	6.1
AVG	**0.5**	**1.1**	**2.5**	**6.1**

Strip Lot. HITACHI	0.52	1.19	2.55	6.13
LK02RD01	0.04	0.07	0.13	0.11
LK02RD02	0.05	0.06	0.12	0.13
LK02RD03	0.06	0.07	0.12	0.13
SD	**0.05**	**0.06**	**0.12**	**0.12**

Strip Lot. HITACHI	0.52	1.19	2.55	6.13
LK02RD01	7.8%	5.8%	5.0%	1.8%
LK02RD02	10.0%	5.4%	4.9%	2.2%
LK02RD03	11.9%	6.3%	4.7%	2.1%
CV	**9.9%**	**5.8%**	**4.9%**	**2.1%**

Exhibit 1
Repeatability Test for Test Strip (Lot No.: LK02RD01)

Conditions: 25°C, 48% RH HCT: 38%

Level 1 – Ketone Concentration: 0.4-0.6 mmol/L Unit: mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	0.51	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
2	0.53	0.5	0.5	0.5	0.5	0.6	0.5	0.5	0.5	0.5	0.5
3	--	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
4	--	0.5	0.5	0.6	0.5	0.5	0.5	0.5	0.5	0.5	0.5
5	--	0.5	0.5	0.5	0.6	0.6	0.5	0.5	0.5	0.5	0.5
6	--	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
7	--	0.6	0.5	0.6	0.5	0.6	0.5	0.6	0.5	0.5	0.5
8	--	0.5	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
9	--	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
10	--	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.4	0.5	0.5
AVG	0.52	0.50	0.49	0.53	0.52	0.54	0.50	0.49	0.48	0.50	0.50
SD	--	0.04	0.04	0.05	0.05	0.04	0.02	0.04	0.03	0.02	0.02
CV	--	8.6%	8.5%	9.7%	9.1%	7.4%	4.6%	7.5%	6.1%	4.0%	4.8%
Average for All Data: 0.5 SD for All Data: 0.04 CV = 7.8%											

Level 2 – Ketone Concentration: 1.0-1.4 mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	1.12	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.1	1.2	1.1
2	1.25	1.1	1.1	1.0	1.2	1.1	1.1	1.2	1.2	1.2	1.1
3	--	1.1	1.1	1.1	1.1	1.0	1.2	1.2	1.2	1.0	1.1
4	--	1.1	1.0	1.2	1.1	1.1	1.1	1.2	1.2	1.1	1.2
5	--	1.1	1.1	1.1	1.1	1.0	1.1	1.2	1.1	1.1	1.1
6	--	1.2	1.2	1.1	1.1	1.2	1.1	1.1	1.2	1.1	1.2
7	--	1.1	1.1	1.1	1.1	1.2	1.1	1.1	1.1	1.1	1.1
8	--	1.0	1.2	1.1	1.2	1.1	1.2	1.1	1.1	1.2	1.1
9	--	1.2	1.2	1.2	1.1	1.2	1.1	1.0	1.1	1.1	1.2
10	--	1.2	1.2	1.2	1.0	1.1	1.1	1.2	1.1	1.2	1.2
AVG	1.19	1.12	1.12	1.12	1.12	1.12	1.13	1.15	1.14	1.12	1.13
SD	--	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
CV	--	6.1%	5.8%	5.9%	6.9%	7.3%	5.1%	6.3%	4.4%	6.4%	5.1%
Average for All Data: 1.1 SD for All Data: 0.07 CV = 5.8%											

Level 3 – Ketone Concentration: 2.2-2.6 mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	2.45	2.4	2.4	2.5	2.5	2.4	2.4	2.6	2.7	2.5	2.7
2	2.65	2.4	2.4	2.3	2.4	2.4	2.4	2.8	2.7	2.5	2.5
3	--	2.5	2.5	2.5	2.4	2.5	2.5	2.6	2.8	2.6	2.6
4	--	2.5	2.5	2.5	2.4	2.4	2.4	2.6	2.6	2.5	2.7
5	--	2.6	2.6	2.6	2.6	2.4	2.4	2.5	2.6	2.4	2.7
6	--	2.5	2.5	2.5	2.5	2.5	2.5	2.6	2.6	2.6	2.5
7	--	2.3	2.3	2.4	2.4	2.6	2.6	2.5	2.7	2.5	2.5
8	--	2.4	2.7	2.4	2.4	2.5	2.5	2.5	2.6	2.8	2.8
9	--	2.5	2.5	2.4	2.5	2.3	2.3	2.6	2.8	2.6	2.6
10	--	2.4	2.4	2.4	2.6	2.5	2.5	2.8	2.8	2.4	2.6
AVG	2.55	2.42	2.46	2.43	2.44	2.42	2.42	2.60	2.66	2.51	2.59
SD	--	0.08	0.12	0.08	0.09	0.07	0.07	0.11	0.10	0.11	0.11
CV	--	3.2%	4.7%	3.2%	3.5%	3.1%	3.1%	4.3%	3.7%	4.5%	4.1%
Average for All Data: 2.5 SD for All Data: 0.13 CV = 5.0%											

Level 4 – Ketone Concentration: 5.7-6.3 mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	6.05	5.9	6.0	6.1	6.1	5.9	5.9	5.9	5.9	5.9	5.9
2	6.21	6.0	6.1	6.2	6.2	6.0	6.0	6.0	6.0	6.0	6.0
3	--	6.0	6.2	6.1	6.1	6.0	6.0	6.0	6.0	5.9	6.1
4	--	5.9	5.9	6.1	6.1	5.9	5.9	6.1	6.1	6.0	6.2
5	--	5.9	5.9	5.9	5.9	5.9	5.9	6.1	6.1	6.0	6.1
6	--	6.0	6.0	6.0	6.1	6.0	6.0	6.1	5.9	6.1	6.2
7	--	6.0	5.9	6.1	6.3	6.0	6.2	6.2	5.9	5.9	5.9
8	--	5.9	6.0	6.2	6.1	5.9	6.3	6.1	6.0	6.1	6.0
9	--	5.9	6.0	6.1	6.1	6.1	6.1	6.1	6.1	6.3	6.0
10	--	6.0	6.1	6.2	6.1	6.2	6.1	5.9	6.1	6.1	5.9
AVG	6.13	5.93	5.99	6.07	6.08	5.97	6.03	6.03	5.99	6.00	6.01
SD	--	0.05	0.09	0.10	0.10	0.10	0.15	0.11	0.09	0.12	0.11
CV	--	0.9%	1.5%	1.6%	1.7%	1.6%	2.5%	1.7%	1.6%	2.0%	1.8%
Average for All Data: 6.0 SD for All Data: 0.11 CV = 1.8%											

Repeatability Test for Test Strip (Lot No.: LK02RD02)

Conditions: 25°C, 48% RH HCT: 38%

Level 1 – Ketone Concentration: 0.4-0.6 mmol/L Unit: mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	0.51	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
2	0.53	0.5	0.5	0.5	0.5	0.6	0.6	0.6	0.5	0.5	0.5
3	--	0.6	0.5	0.5	0.5	0.5	0.7	0.5	0.5	0.5	0.5
4	--	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
5	--	0.5	0.5	0.5	0.6	0.5	0.5	0.5	0.5	0.6	0.5
6	--	0.5	0.5	0.5	0.6	0.5	0.6	0.5	0.5	0.5	0.6
7	--	0.7	0.6	0.5	0.6	0.7	0.7	0.5	0.5	0.6	0.5
8	--	0.7	0.6	0.5	0.5	0.7	0.6	0.5	0.6	0.5	0.5
9	--	0.6	0.5	0.5	0.5	0.5	0.6	0.5	0.5	0.5	0.5
10	--	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
AVG	0.52	0.56	0.51	0.50	0.53	0.55	0.58	0.51	0.51	0.51	0.49
SD	--	0.07	0.04	0.02	0.04	0.07	0.07	0.03	0.03	0.05	0.03
CV	--	12.0%	8.2%	4.1%	8.2%	12.3%	12.0%	5.3%	5.2%	8.9%	5.1%
Average for All Data: 0.5 SD for All Data: 0.05 CV = 10.0%											

Level 2 – Ketone Concentration 1.0-1.4 mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	1.12	1.2	1.1	1.1	1.2	1.2	1.1	1.0	1.1	1.1	1.1
2	1.25	1.1	1.0	1.2	1.1	1.2	1.2	1.1	1.1	1.1	1.1
3	--	1.2	1.0	1.2	1.2	1.2	1.1	1.0	1.1	1.1	1.2
4	--	1.1	1.1	1.1	1.1	1.2	1.2	1.1	1.0	1.1	1.2
5	--	1.2	1.2	1.2	1.1	1.2	1.1	1.1	1.1	1.2	1.2
6	--	1.0	1.2	1.1	1.2	1.1	1.2	1.2	1.1	1.0	1.0
7	--	1.2	1.2	1.1	1.1	1.1	1.1	1.2	1.1	1.1	1.2
8	--	1.1	1.1	1.1	1.3	1.1	1.2	1.1	1.1	1.1	1.0
9	--	1.1	1.1	1.2	1.1	1.2	1.1	1.1	1.0	1.2	1.1
10	--	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
AVG	1.19	1.11	1.11	1.14	1.15	1.15	1.11	1.07	1.07	1.10	1.11
SD	--	0.07	0.05	0.04	0.05	0.03	0.06	0.05	0.05	0.04	0.09
CV	--	6.0%	4.4%	3.5%	4.6%	2.8%	5.0%	4.7%	5.1%	4.0%	8.1%
Average for All Data: 1.1 SD for All Data: 0.06 CV = 5.4%											

Level 3 – Ketone Concentration 2.2-2.6 mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	2.45	2.7	2.6	2.5	2.7	2.4	2.4	2.4	2.6	2.6	2.6
2	2.65	2.4	2.7	2.5	2.7	2.4	2.4	2.4	2.6	2.5	2.5
3	--	2.7	2.7	2.6	2.6	2.4	2.4	2.6	2.6	2.6	2.6
4	--	2.6	2.5	2.5	2.7	2.4	2.5	2.5	2.7	2.5	2.6
5	--	2.6	2.6	2.5	2.6	2.4	2.6	2.5	2.6	2.8	2.8
6	--	2.6	2.7	2.6	2.5	2.5	2.5	2.5	2.4	2.4	2.4
7	--	2.5	2.5	2.5	2.6	2.6	2.6	2.8	2.8	2.5	2.5
8	--	2.5	2.6	2.8	2.8	2.5	2.5	2.5	2.5	2.4	2.4
9	--	2.3	2.7	2.6	2.6	2.3	2.3	2.3	2.6	2.6	2.7
10	--	2.5	2.6	2.4	2.6	2.5	2.5	2.4	2.7	2.8	2.7
AVG	2.55	2.52	2.60	2.51	2.62	2.42	2.44	2.47	2.58	2.54	2.55
SD	--	0.12	0.08	0.11	0.08	0.07	0.09	0.13	0.10	0.15	0.14
CV	--	4.7%	3.1%	4.5%	3.0%	3.1%	3.6%	5.3%	3.9%	6.0%	5.5%
Average for All Data: 2.5 SD for All Data: 0.12 CV = 4.9%											

Level 4 – Ketone Concentration 5.7-6.3 mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	6.05	6.0	6.1	6.1	6.1	6.1	5.9	6.1	6.3	6.0	5.8
2	6.21	5.9	5.9	6.1	6.2	6.0	6.2	6.4	6.1	5.9	6.2
3	--	5.9	5.9	5.9	5.9	5.9	6.1	6.3	5.9	5.9	6.1
4	--	5.8	6.0	6.2	6.0	6.0	6.0	6.0	6.0	6.0	6.2
5	--	6.0	5.8	6.1	6.0	6.0	6.0	6.2	6.1	5.9	6.0
6	--	5.9	5.9	6.3	6.0	6.2	6.0	5.9	5.9	5.9	6.1
7	--	5.9	6.1	6.1	5.9	5.8	6.1	6.3	6.1	6.0	6.2
8	--	5.8	5.8	6.1	6.0	6.0	6.0	6.0	5.9	6.1	6.1
9	--	5.9	5.9	6.1	5.9	5.9	6.3	6.1	6.0	5.8	6.1
10	--	6.0	6.1	5.9	5.9	5.9	5.8	6.1	6.0	6.1	5.9
AVG	6.13	5.89	5.92	6.06	5.97	5.96	6.03	6.12	6.00	5.95	6.04
SD	--	0.07	0.12	0.13	0.10	0.12	0.15	0.15	0.12	0.10	0.13
CV	--	1.1%	2.1%	2.1%	1.7%	2.0%	2.4%	2.5%	2.0%	1.6%	2.1%
Average for All Data: 6.0 SD for All Data: 0.13 CV = 2.2%											

Repeatability Test for Test Strip (Lot No.: LK02RD03)

Conditions: 25°C, 48% RH HCT: 38%

Level 1 – Ketone Concentration: 0.4-0.6 mmol/L Unit: mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	0.51	0.5	0.5	0.5	0.5	0.5	0.6	0.6	0.4	0.4	0.4
2	0.53	0.4	0.4	0.5	0.5	0.5	0.7	0.5	0.5	0.4	0.4
3	--	0.6	0.5	0.5	0.4	0.5	0.5	0.5	0.5	0.4	0.5
4	--	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.4
5	--	0.5	0.5	0.5	0.5	0.4	0.6	0.5	0.4	0.5	0.4
6	--	0.4	0.4	0.5	0.6	0.5	0.7	0.5	0.5	0.5	0.5
7	--	0.6	0.6	0.5	0.5	0.6	0.6	0.5	0.5	0.6	0.4
8	--	0.6	0.5	0.5	0.4	0.6	0.6	0.5	0.5	0.4	0.4
9	--	0.5	0.4	0.5	0.5	0.5	0.5	0.5	0.4	0.5	0.5
10	--	0.5	0.4	0.5	0.5	0.4	0.5	0.5	0.4	0.4	0.4
AVG	0.52	0.51	0.46	0.50	0.48	0.50	0.58	0.51	0.46	0.46	0.44
SD	--	0.07	0.04	0.02	0.04	0.07	0.07	0.03	0.03	0.05	0.03
CV	--	13.2%	9.1%	4.4%	9.0%	13.6%	12.0%	5.3%	5.8%	9.9%	5.7%
Average for All Data: 0.49 SD for All Data: 0.06 CV = 11.9%											

Level 2 – Ketone Concentration: 1.0-1.4 mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	1.12	1.2	1.1	1.1	1.1	1.1	1.0	1.0	1.0	1.0	1.0
2	1.25	1.1	1.0	1.1	1.1	1.1	1.1	1.0	1.0	1.0	1.0
3	--	1.1	1.0	1.2	1.2	1.1	1.0	0.9	1.0	1.0	1.1
4	--	1.1	1.1	1.1	1.1	1.1	1.1	1.0	0.9	1.0	1.1
5	--	1.1	1.1	1.1	1.1	1.1	1.0	1.0	1.0	1.1	1.1
6	--	1.0	1.1	1.1	1.2	1.1	1.1	1.1	1.0	0.9	0.9
7	--	1.1	1.1	1.1	1.1	1.1	1.0	1.1	1.0	1.0	1.1
8	--	1.0	1.1	1.1	1.2	1.1	1.1	1.0	1.0	1.0	0.9
9	--	1.0	1.1	1.2	1.1	1.1	1.0	1.0	0.9	1.1	1.0
10	--	1.1	1.1	1.1	1.1	1.1	1.0	1.0	1.0	1.0	1.0
AVG	1.19	1.06	1.06	1.09	1.10	1.10	1.03	0.99	0.99	1.02	1.03
SD	--	0.07	0.05	0.04	0.05	0.03	0.06	0.05	0.05	0.04	0.09
CV	--	6.3%	4.6%	3.7%	4.8%	2.9%	5.4%	5.1%	5.5%	4.3%	8.7%
Average for All Data: 1.0 SD for All Data: 0.07 CV = 6.3%											

Level 3 – Ketone Concentration: 2.2-2.6 mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	2.45	2.7	2.6	2.6	2.8	2.5	2.7	2.7	2.6	2.7	2.5
2	2.65	2.5	2.7	2.7	2.7	2.7	2.7	2.8	2.7	2.6	2.6
3	--	2.6	2.6	2.8	2.6	2.7	2.6	2.6	2.6	2.7	2.7
4	--	2.7	2.6	2.7	2.9	2.9	2.6	2.7	2.9	2.9	2.6
5	--	2.6	2.6	2.5	2.5	2.5	2.4	2.8	2.7	2.7	2.4
6	--	2.7	2.9	2.9	2.6	2.6	2.6	2.7	2.5	2.7	2.6
7	--	2.6	2.6	2.6	2.5	2.5	2.5	2.5	2.7	2.7	2.7
8	--	2.4	2.4	2.7	2.7	2.8	2.5	2.5	2.7	2.6	2.6
9	--	2.6	2.5	2.8	2.9	2.8	2.8	2.8	2.7	2.7	2.5
10	--	2.5	2.8	2.6	2.8	2.5	2.8	2.7	2.6	2.8	2.5
AVG	2.55	2.57	2.61	2.66	2.67	2.62	2.60	2.66	2.63	2.68	2.55
SD	--	0.09	0.13	0.11	0.16	0.16	0.13	0.13	0.11	0.08	0.08
CV	--	3.6%	4.9%	4.3%	6.0%	6.2%	4.9%	4.8%	4.2%	3.1%	3.1%
Average for All Data: 2.6 SD for All Data: 0.12 CV = 4.7%											

Level 4 – Ketone Concentration: 5.7-6.3 mmol/L

Repeat	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10
1	6.05	6.1	6.3	6.4	6.5	6.3	6.5	6.3	6.2	6.0	6.3
2	6.21	6.3	6.3	6.3	6.4	6.1	6.1	6.1	6.0	6.1	6.3
3	--	6.0	6.2	6.1	6.1	6.5	6.3	6.1	6.1	6.1	6.3
4	--	6.3	6.0	6.1	6.3	6.0	6.2	6.1	6.2	6.2	6.1
5	--	6.3	6.2	6.1	6.0	6.1	6.2	6.3	6.4	6.1	6.4
6	--	6.3	6.1	6.0	6.3	6.0	6.0	6.2	6.2	6.3	5.9
7	--	6.0	6.0	5.9	5.9	6.0	6.0	6.0	6.3	6.1	6.1
8	--	6.1	6.1	6.0	6.0	6.0	6.1	6.3	6.2	6.0	6.0
9	--	6.1	6.1	6.1	6.2	6.1	5.9	6.3	6.0	6.1	6.1
10	--	6.1	6.3	6.1	6.3	6.1	6.1	6.0	6.4	6.1	6.0
AVG	6.13	6.15	6.16	6.11	6.20	6.11	6.14	6.16	6.20	6.12	6.14
SD	--	0.11	0.11	0.12	0.18	0.15	0.16	0.11	0.14	0.08	0.15
CV	--	1.9%	1.7%	1.9%	2.9%	2.5%	2.6%	1.8%	2.2%	1.3%	2.5%
Average for All Data: 6.1 SD for All Data: 0.13 CV = 2.1%											

Precision Evaluation

Scope and Objective

The objective of this study was designed to evaluate the repeatability of the InSight Keto Vet Meter.

Precision evaluation was performed using control solutions with two different ketone concentrations. This evaluation was a 10 day study. For each ketone concentration, a measurement was carried out on a meter for each lot of test strips per day. A total of 30 meters were tested each day. The control solution concentrations were determined by the HITACHI 704 Automatic Analyser.

The meters were checked according to the user guide before each test to make sure that they were in normal working condition. The HITACHI 704 Automatic Analyser was calibrated prior to each test using the standard reference RANDOX assay kit.

Materials

- 30 InSight Keto Vet Meters: SN eB-K04RD01~30
- 3 Lots of InSight Keto Vet Test Strips, 40 Vials Per Lot (10 Test Strips/Vial: Lot No. LK02RD01~3
- Code Card
- Control Solution: Lot No. I2C0A1H01
- HITACHI 704 Automatic Analyser
- Standard Reference: RANDOX Assay Kit (RB1007)

Test Protocol

Sample Preparation: The two ketone concentrations of the control solutions are within the following ranges:

- 0.4~0.6 mmol/L
- 2.2~2.4 mmol/L

1. Use the HITACHI reference method to determine the ketone level of all control solutions.
2. Meters should be checked according to the user guide to make sure that the meters are in normal working condition.
3. The test conditions should be:
   - Temperature 23°C±2°C
   - Humidity 30%~85%
   - Check conditions before each test and every hour during test. If conditions are within specification, continue testing. If test conditions are not within the specification, stop testing and repeat all tests since last approved condition check.
   - Steps 4-14 should be carried out using two people, one person is responsible for the operation of all the test steps and the other one is responsible for recording the test results.
4. For each test, time and ketone readings should be recorded. All data should be written correctly and should be easily distinguished between the association of the readings and the meters.
5. After each test, remove and discard the test strip.
6. Precision Evaluation: This evaluation was performed using control solutions with two different ketone concentrations. This evaluation was a 10 day study. For each ketone concentration, a measurement was conducted on a meter for each lot of test strips per day. A total of 30 meters were tested each day.

7. Obtain the required materials and equipment.
8. Record the serial numbers of the InSight Keto Vet Meters, the Lot No. of each vial of InSight Keto Vet Test Strips and the Lot No. of all InSight Keto Vet Control Solutions.
9. Each level of sample was confirmed by the HITACHI 704 Automatic Analyser with the RANDOX Assay Kit (RB1007) and the equivalent digital reading was recorded.
10. Insert the InSight Keto Vet Test Strip into the meter. Apply a drop of the control solution, with a ketone concentration adjusted within the range of 0.4~0.6 mmol/L, on the test zone of the test strip and wait for the test result. Repeat this experiment 10 times for each meter.
11. Repeat step 10 for the other control solutions with ketone concentration of 2.2~2,4 mmol/L, respectively.
12. Repeat steps 10-11 for the other two lots of the test strips.
13. Repeat steps 9-12 for ten days.
14. Documentation Review: Review data recordings for data completeness and accuracy.

Acceptance Criteria

The results of this precision evaluation were analysed:
Blood Ketone Concentration: <1.5 mmol/L, SD*<0.15 mmol/L
Blood Ketone Concentration ≥1.5 mmol/L, CV*<6%

Test Results

Exhibit 2 shows the results for the precision tests. The intermediate precision evaluation for each of the three lots of strips in three ketone concentrations is generally:

1. For ketone concentrations <1.5 mmol/L: Standard Deviation (SD) for the readings of each meter is <0.15 mmol/L.
2. For ketone concentrations ≥1.5 mmol/L: Coefficient of Variation (CV) for the readings of each meter within a range of 6%.

Average (AVG), Standard Deviation (SD), and Coefficient of Variation (CV) for Each Combination of Ketone Concentration and Strip Lot

Unit: mmol/L

HITACHI Strip Lot.	0.52	2.29
LK02RD01	0.6	2.1
LK02RD02	0.5	2.3
LK02RD03	0.5	2.2
AVG	**0.5**	**2.2**

HITACHI Strip Lot.	0.52	2.29
LK02RD01	0.06	0.11
LK02RD02	0.05	0.11
LK02RD03	0.05	0.10
SD	**0.05**	**0.11**

HITACHI Strip Lot.	0.52	2.29
LK02RD01	10.0%	5.2%
LK02RD02	10.0%	5.0%
LK02RD03	9.7%	4.5%
CV	**9.9%**	**4.9%**

Exhibit 2

Precision Evaluation for Test Strip (Lot No: LK02RD01)

Level 1 – Ketone Concentration: 0.4-0.6 mmol/L Unit: mmol/L

	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10	Operator
	0.51	0.6	0.5	0.6	0.5	0.6	0.5	0.6	0.5	0.6	0.5	A
	0.50	0.5	0.5	0.6	0.5	0.6	0.5	0.6	0.5	0.6	0.6	B
	0.52	0.6	0.5	0.5	0.4	0.6	0.5	0.5	0.6	0.6	0.6	C
	0.52	0.6	0.6	0.6	0.5	0.6	0.6	0.6	0.6	0.6	0.6	A
	0.51	0.5	0.6	0.6	0.5	0.6	0.6	0.6	0.5	0.6	0.6	B
	0.54	0.5	0.5	0.6	0.6	0.6	0.6	0.5	0.4	0.6	0.5	C
	0.50	0.5	0.5	0.6	0.5	0.6	0.5	0.6	0.5	0.6	0.5	A
	0.52	0.4	0.6	0.6	0.5	0.5	0.6	0.6	0.6	0.6	0.6	B
	0.53	0.5	0.6	0.5	0.6	0.6	0.6	0.6	0.5	0.6	0.5	C
	0.51	0.5	0.5	0.6	0.6	0.5	0.6	0.5	0.6	0.6	0.6	A
AVG	0.52	0.52	0.54	0.58	0.52	0.58	0.56	0.57	0.53	0.60	0.56	
SD	0.01	0.06	0.05	0.04	0.06	0.04	0.05	0.05	0.07	0.00	0.05	
CV	2.5%	11.4%	9.6%	7.3%	12.2%	7.3%	9.2%	8.5%	12.7%	0.0%	9.2%	
Average for All Data: **0.56** SD for All Data: **0.06** CV = **10.0%**												

Level 2 – Ketone Concentration: 2.2-2.4 mmol/L

	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10	Operator
	2.27	2.0	2.2	2.0	2.1	2.1	2.3	2.2	2.2	2.2	2.2	A
	2.30	2.3	2.2	2.0	2.2	2.2	2.3	2.1	2.3	2.1	2.2	B
	2.26	2.2	2.0	2.0	2.3	2.2	2.2	2.1	2.1	2.2	2.1	C
	2.29	2.3	1.9	2.1	2.1	2.1	2.4	2.0	2.2	2.3	2.3	A
	2.31	2.1	2.1	1.9	2.2	2.2	2.3	2.0	2.3	2.2	2.2	B
	2.30	2.1	2.1	2.2	2.1	2.3	2.2	2.1	2.0	2.3	2.1	C
	2.28	2.2	2.0	2.1	2.1	2.0	2.0	2.0	2.0	2.0	2.2	A
	2.30	2.1	2.1	2.2	2.0	2.1	2.2	2.2	2.3	2.3	2.0	B
	2.27	2.0	2.1	2.0	2.2	2.2	2.3	2.1	2.2	2.4	2.0	C
	2.32	2.2	1.9	2.2	2.1	2.0	2.1	2.1	2.2	2.1	2.2	A
AVG	2.29	2.15	2.06	2.07	2.14	2.14	2.23	2.09	2.18	2.21	2.15	
SD	0.02	0.11	0.11	0.11	0.08	0.10	0.12	0.07	0.11	0.12	0.10	
CV	0.8%	5.0%	5.2%	5.1%	3.9%	4.5%	5.2%	3.5%	5.2%	5.4%	4.5%	
Average for All Data: **2.14** SD for All Data: **0.11** CV = **5.2%**												

Precision Evaluation for Test Strip (Lot No: LK02RD02)

Level 1 – Ketone Concentration: 0.4-0.6 mmol/L

Unit: mmol/L

	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10	Operator
	0.51	0.5	0.6	0.5	0.5	0.5	0.5	0.4	0.5	0.5	0.6	B
	0.50	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.6	0.5	0.5	C
	0.52	0.5	0.6	0.5	0.5	0.5	0.5	0.5	0.6	0.4	0.5	A
	0.52	0.5	0.5	0.5	0.6	0.4	0.5	0.4	0.5	0.5	0.5	B
	0.51	0.5	0.5	0.5	0.5	0.4	0.5	0.5	0.5	0.5	0.5	C
	0.54	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.6	0.5	0.5	A
	0.50	0.6	0.5	0.5	0.6	0.5	0.6	0.5	0.6	0.5	0.5	B
	0.52	0.6	0.5	0.4	0.5	0.5	0.5	0.5	0.5	0.4	0.5	C
	0.53	0.5	0.5	0.5	0.6	0.5	0.6	0.4	0.5	0.5	0.6	A
	0.51	0.5	0.6	0.5	0.5	0.5	0.6	0.5	0.5	0.4	0.5	B
AVG	0.52	0.52	0.53	0.49	0.53	0.48	0.53	0.47	0.54	0.47	0.52	
SD	0.01	0.04	0.05	0.03	0.05	0.04	0.05	0.05	0.05	0.05	0.04	
CV	2.5%	8.1%	9.1%	6.5%	9.1%	8.8%	9.1%	10.3%	9.6%	10.3%	8.1%	
Average for All Data: **0.51** SD for All Data: **0.05** CV = **10.0%**												

Level 2 – Ketone Concentration: 2.2-2.4 mmol/L

	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10	Operator
	2.27	2.4	2.3	2.3	2.2	2.4	2.5	2.4	2.2	2.3	2.2	B
	2.30	2.2	2.1	2.2	2.2	2.2	2.2	2.3	2.1	2.1	2.3	C
	2.26	2.3	2.2	2.3	2.3	2.5	2.5	2.1	2.4	2.4	2.2	A
	2.29	2.3	2.2	2.4	2.3	2.3	2.4	2.4	2.2	2.3	2.1	B
	2.31	2.1	2.3	2.3	2.1	2.3	2.2	2.2	2.4	2.2	2.3	C
	2.30	2.2	2.5	2.3	2.2	2.2	2.2	2.1	2.3	2.5	2.1	A
	2.28	2.1	2.3	2.2	2.2	2.5	2.3	2.4	2.2	2.2	2.3	B
	2.30	2.3	2.4	2.3	2.4	2.1	2.4	2.3	2.4	2.2	2.1	C
	2.27	2.3	2.1	2.2	2.3	2.2	2.4	2.3	2.1	2.3	2.3	A
	2.32	2.3	2.3	2.2	2.4	2.4	2.2	2.1	2.4	2.2	2.1	B
AVG	2.29	2.25	2.27	2.27	2.26	2.31	2.33	2.26	2.27	2.27	2.20	
SD	0.02	0.10	0.13	0.07	0.10	0.14	0.13	0.13	0.13	0.12	0.09	
CV	0.8%	4.3%	5.5%	3.0%	4.3%	5.9%	5.4%	5.6%	5.5%	5.1%	4.3%	
Average for All Data: **2.27** SD for All Data: **0.11** CV = **5.0%**												

Precision Evaluation for Test Strip (Lot No: LK02RD03)

Level 1 – Ketone Concentration: 0.4-0.6 mmol/L Unit: mmol/L

	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10	Operator
	0.51	0.5	0.5	0.5	0.5	0.4	0.5	0.5	0.4	0.5	0.6	C
	0.50	0.5	0.5	0.5	0.5	0.5	0.5	0.6	0.4	0.5	0.5	A
	0.52	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	B
	0.52	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.4	C
	0.51	0.5	0.4	0.5	0.6	0.5	0.5	0.5	0.5	0.6	0.4	A
	0.54	0.5	0.5	0.5	0.5	0.4	0.5	0.5	0.5	0.6	0.5	B
	0.50	0.4	0.5	0.5	0.5	0.4	0.5	0.6	0.4	0.5	0.5	C
	0.52	0.5	0.5	0.6	0.5	0.5	0.5	0.5	0.5	0.5	0.5	A
	0.53	0.4	0.5	0.6	0.5	0.5	0.6	0.6	0.5	0.5	0.5	B
	0.51	0.5	0.5	0.5	0.6	0.4	0.5	0.5	0.5	0.5	0.5	C
AVG	0.52	0.48	0.49	0.52	0.52	0.46	0.51	0.53	0.47	0.52	0.49	
SD	0.01	0.04	0.03	0.04	0.04	0.05	0.03	0.05	0.05	0.04	0.06	
CV	2.5%	8.8%	6.5%	8.1%	8.1%	11.2%	6.2%	9.1%	10.3%	8.1%	11.6%	
Average for All Data: **0.50** SD for All Data: **0.05** CV = **9.7%**												

Level 2 – Ketone Concentration: 2.2-2.4 mmol/L

	HITACHI	eB-K04RD01	eB-K04RD02	eB-K04RD03	eB-K04RD04	eB-K04RD05	eB-K04RD06	eB-K04RD07	eB-K04RD08	eB-K04RD09	eB-K04RD10	Operator
	2.27	2.1	2.4	2.2	2.1	2.3	2.1	2.2	2.3	2.2	2.1	C
	2.30	2.3	2.2	2.1	2.2	2.2	2.1	2.1	2.2	2.2	2.1	A
	2.26	2.2	2.1	2.3	2.1	2.1	2.1	2.3	2.3	2.1	2.0	B
	2.29	2.1	2.2	2.2	2.2	2.2	2.1	2.1	2.2	2.1	2.3	C
	2.31	2.0	2.0	2.2	2.2	2.0	2.1	2.1	2.2	2.3	2.2	A
	2.30	2.1	2.2	2.3	2.3	2.3	2.4	2.0	2.3	2.2	2.2	B
	2.28	2.3	2.1	2.4	2.1	2.1	2.1	2.0	2.1	2.2	2.1	C
	2.30	2.2	2.0	2.3	2.2	2.0	2.2	2.2	2.2	2.1	2.2	A
	2.27	2.1	2.0	2.2	2.3	2.2	2.3	2.1	2.2	2.1	2.1	B
	2.32	2.3	2.2	2.3	2.1	2.2	2.1	2.3	2.0	2.2	2.1	C
AVG	2.29	2.17	2.14	2.25	2.18	2.16	2.16	2.14	2.20	2.17	2.14	
SD	0.02	0.11	0.13	0.08	0.08	0.11	0.11	0.11	0.09	0.07	0.08	
CV	0.8%	4.9%	5.9%	3.8%	3.6%	5.0%	5.0%	5.0%	4.3%	3.1%	3.9%	
Average for All Data: **2.17** SD for All Data: **0.10** CV = **4.5%**												

Conclusion

The repeatability evaluation and precision study indicates InSight Keto Vet Meters meets the precision acceptance criteria of <1.5 mmol/L ketone concentration, SD <0.15 mmol/L and of ≥1.5 mmol/L, CV≤6% respectively, suggesting that InSight Keto Vet provides reproducible run-to-run measurements.