InSight Keto Vet
Clinical/Accuracy Evaluation Report

Scope and Objective
The objective of this study was to clinically evaluate the InSight Keto Vet Meter.

This study is intended to evaluate the overall system efficacy of the InSight Keto Vet Meter performed by the user.

Materials
- InSight Keto Vet Meter: SN eB-K04RD01, SN eB-K04RD02 and SN eB-K04RD03
- InSight Keto Vet Test Strip: Lot No. LK02RD001 (Code: 601)
- Optium Ketone Meter: SN XEGW082-P070D
- Optium Ketone Test Strip: Lot No. 75001H39 and Lot No. 75001H48
- HITACHI 704 Automatic Biochemical Analyser

Subjects
The clinical/accuracy study was performed using venous blood samples collected from 110 different cattle. The report contains a total of 110 cattle samples, of which 10 altered samples were spiked with high ketone concentrations (subjects 101-110).

The ketone concentrations of venous blood samples were measured using two InSight Keto Vet Meters and the HITACHI 704 Automatic Biochemical Analyser, respectively. The venous blood sample was collected from the cattle into sodium heparin vacutainers.
110 different cattle samples whose HCT is in the range of 20% ~ 60%.

Sample Collection
Blood collection from the tail vein of cattle by the veterinarian.

Measurement Procedures

Clinical Evaluation
Correlation Test
1. The InSight Keto Vet Meter was operated by a technician and the test strips were taken from 1 batch (Lot No. eB-LK02RD001).
2. The blood sample was collected from the tail vein of the cattle and tested on the InSight Keto Vet Meter. Result recorded.
3. 5ml venous blood was collected from the tail vein of the cattle, then the sample is dispensed into a tube with sodium heparin and gently inverted. Confirm the cattle haematocrit and measure BHB concentration using the HITACHI 704 Automatic Analyser.
4. Record the cattle's information and their measuring results.
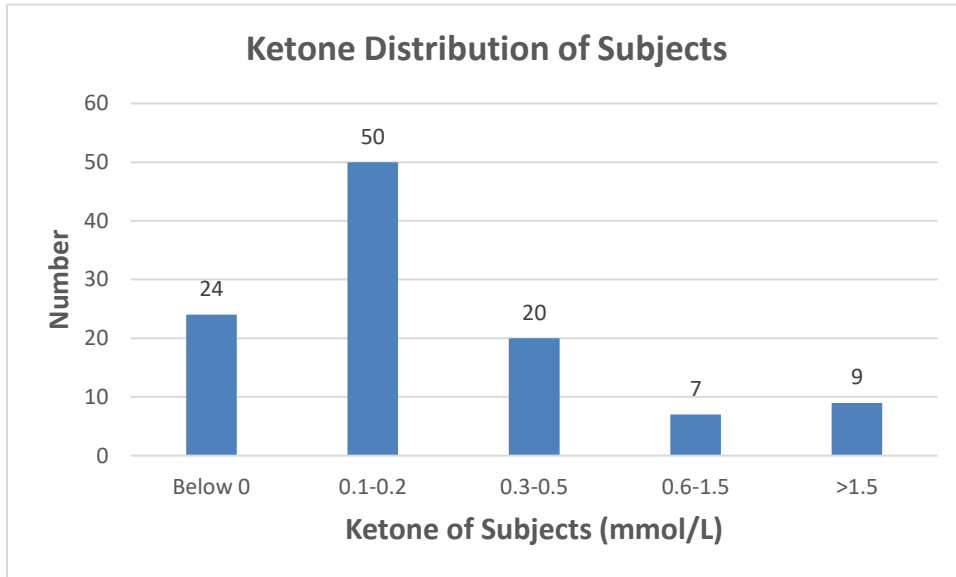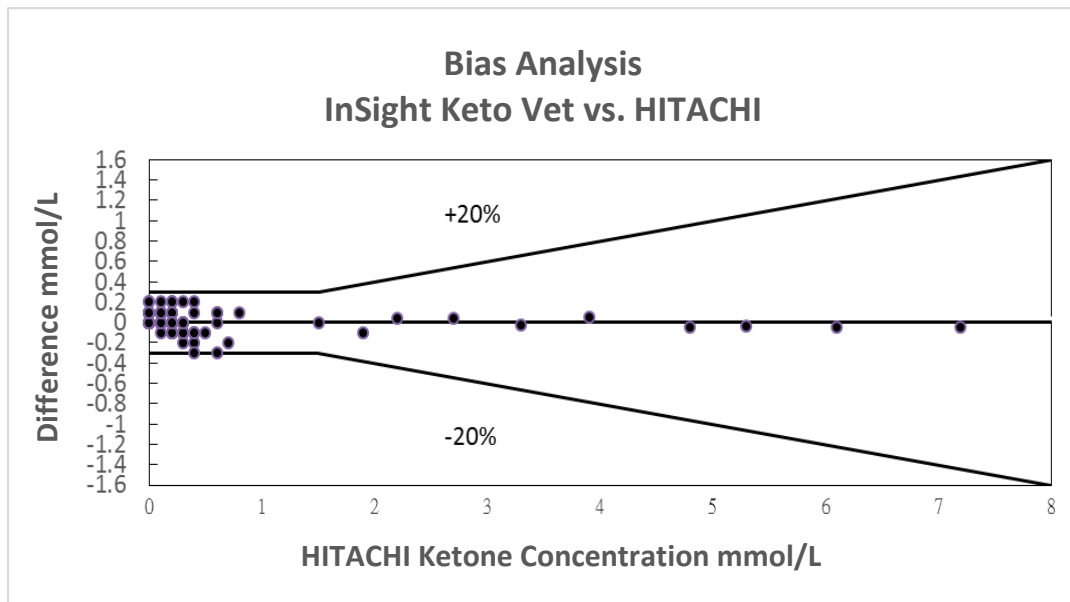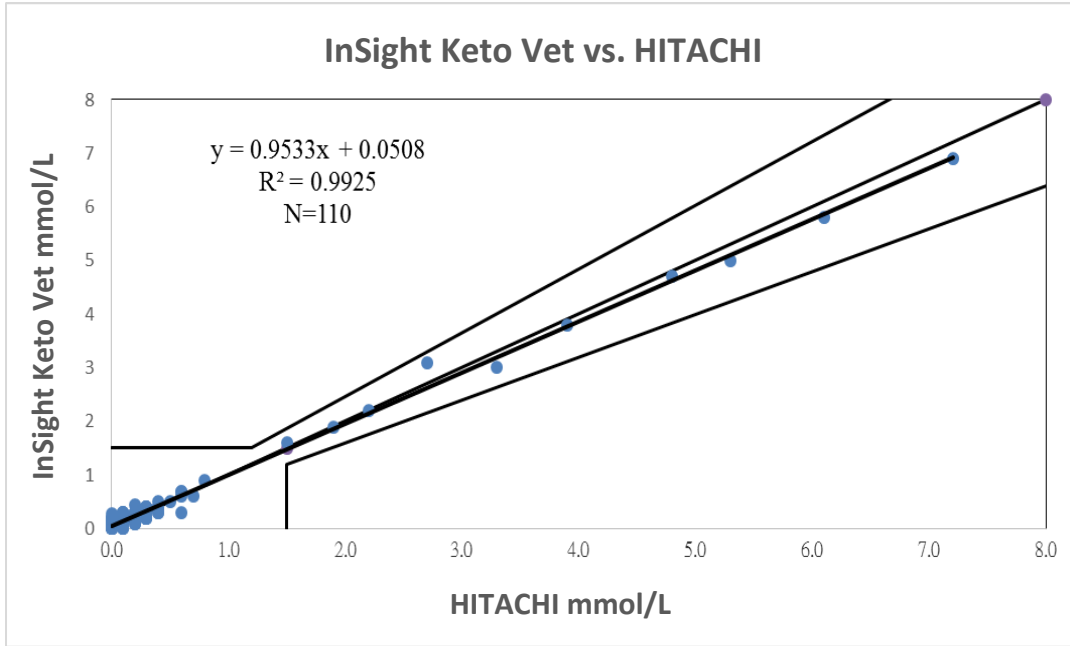
Field Test
1. Collect the venous blood sample from the tail vein of the cattle selected randomly.
2. The venous blood sample should be measured using the InSight Keto Vet Meters.
3. The procedure is completed for at least 1 batch of InSight Keto Vet Test Strips.
4. Record the cattle's information and their measuring results.
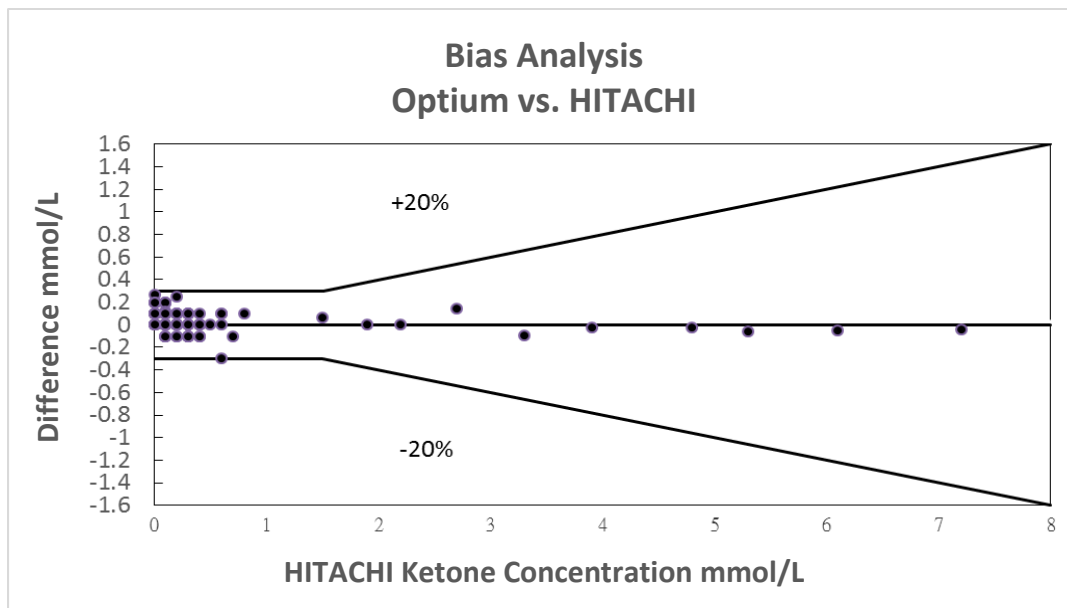
Acceptance Criteria
Ketone Concentration: <1.5 mmol/L, Difference ≤±0.3 mmol/L
$\qquad\qquad\qquad$ ≥1.5 mmol/L, Bias% <20%

Distribution of Subjects

InSight Keto Vet vs. HITACHI

$$y = 0.9533x + 0.0508$$
$$R^2 = 0.9925$$
$$N=110$$

(x-axis: HITACHI mmol/L; y-axis: InSight Keto Vet mmol/L)

Bias Analysis
InSight Keto Vet vs. HITACHI

+20%

-20%

(x-axis: HITACHI Ketone Concentration mmol/L; y-axis: Difference mmol/L)

Optium vs. HITACHI

$y = 0.9619x + 0.0251$
$R^2 = 0.9923$
$N=110$

Optium mmol/L (y-axis)

HITACHI mmol/L (x-axis)

Bias Analysis
Optium vs. HITACHI

+20%

-20%

Difference mmol/L (y-axis)

HITACHI Ketone Concentration mmol/L (x-axis)

Data Examination

InSight Keto Vet vs. HITACHI 704 Automatic Analyser
The analysis is also applied to monitor the InSight Keto Vet accuracy in this investigation. The test results measured by InSight Keto Vet is plotted against the readings obtained by the HITACHI 704 Automatic Analyser. All of the data falls within the acceptable area.

InSight Keto Vet vs. HITACHI 704 Automatic Analyser
The linear regression analysis was assessed by comparing the InSight Keto Vet readings performed by the technician with the reference values using the HITACHI 704 Automatic Analyser. The results shown below are from a total of 110 samples.

Number of Samples	Slope	Intercept	R^2
110	0.9533	0.0508	0.9925

InSight Keto Vet vs. HITACHI 704 Automatic Analyser

<1.5 mmol/L	N=100		
Within ±0.1 mmol/L	Within ±0.2 mmol/L	Within ±0.3 mmol/L	
88/100 (88%)	97/100 (97%)	100/100 (100%)	
≥1.5 mmol/L	N=10		
Within ±5%	Within ±10%	Within ±15%	Within ±20%
8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)

Conclusion
The InSight Keto Vet Meter is accurate compared to other methods. The total difference and bias of test results are within 0.3 mmol/L and 15%.