



CentriVet Blood Glucose and Ketone Monitoring System

CentriVet Blood Ketone Strip Canine Whole Blood Sample

Accuracy Study Report

Azure Institute
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	Department	Signature	Date
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Reviewer	G-strip R&D	Muler Wang	2016.10.28
Approval	G-strip R&D	Blair Liu	2016.10.28

1.0 Objective

The objective of the accuracy study is to demonstrate that the accuracy of the CentriVet Blood Glucose and Ketone Monitoring System – CentriVet Blood Ketone Strip with canine whole blood samples, when compared to a laboratory reference measurement method, meets the accuracy acceptance criteria.

2.0 Methods

Canine whole blood samples (individual bleeds) were obtained from BioChemed Services (Winchester, VA). For each sample, concentration of D-3-hydroxybutyrate (β -ketone) was measured with a reference method and CentriVet Blood Glucose and Ketone Monitoring System with CentriVet Blood Ketone strip for comparison. Additionally, canine whole blood samples were spiked with D-3-hydroxybutyrate (β -ketone) to obtain samples with high concentration of D-3-hydroxybutyrate (β -ketone).

Study Site:

The accuracy study was conducted at AZURE Institute, San Diego, California, USA.

Number of Subjects

All canine blood samples were drawn from 15 individual canines.

Sample Type:

Canine whole blood samples were drawn and injected into a blood collection tube with sodium heparin anticoagulant.

Reference Method:

Procedures were followed according to instructions given in Randox D-3-Hydroxybutyrate (Ranbut) Reagent package insert to prepare samples. Measurements were taken using Spectronic Genesys 6 UV-Visible Spectrophotometer.

Tested D-3-Hydroxybutyrate (β -Ketone) Concentration Range:

The tested D-3-hydroxybutyrate (β -ketone) concentration range is from 0.3 to 7.3 mmol/L

The subject blood hematocrit range is from 30% to 46%.

Number of Strip Lots and Meters:

3 strip lots were tested for the study. Strip lot KE160518C-1, KE160614C-1 and KE160614D-1.

6 meters were used for the study. The meter serial numbers are listed in the following table.

	Meter Serial #
1	502B000287B
2	502B00028B0
3	502B000287F
4	502B00028A2
5	502B00028B3
6	502B0002884

Code Chips:

Code chips are specific for canine blood sample with CentriVet Blood Ketone Strips.

Environmental Conditions:

The study site is an air condition controlled facility and the nominal temperature was around 73°F.

Subject Selection Criteria:

All canine blood samples were drawn from adult dogs that were fasted for 8 or more hours prior to collection.

3.0 Acceptance Criteria

95 % of the measured values shall fall within either ± 0.3 mmol/L of the average measured values of the reference measurement at D-3-hydroxybutyrate (β -ketone) concentrations < 1.5 mmol/L or within $\pm 20\%$ of the average measured values of the reference measurement at D-3-hydroxybutyrate (β -ketone) concentrations ≥ 1.5 mmol/L.

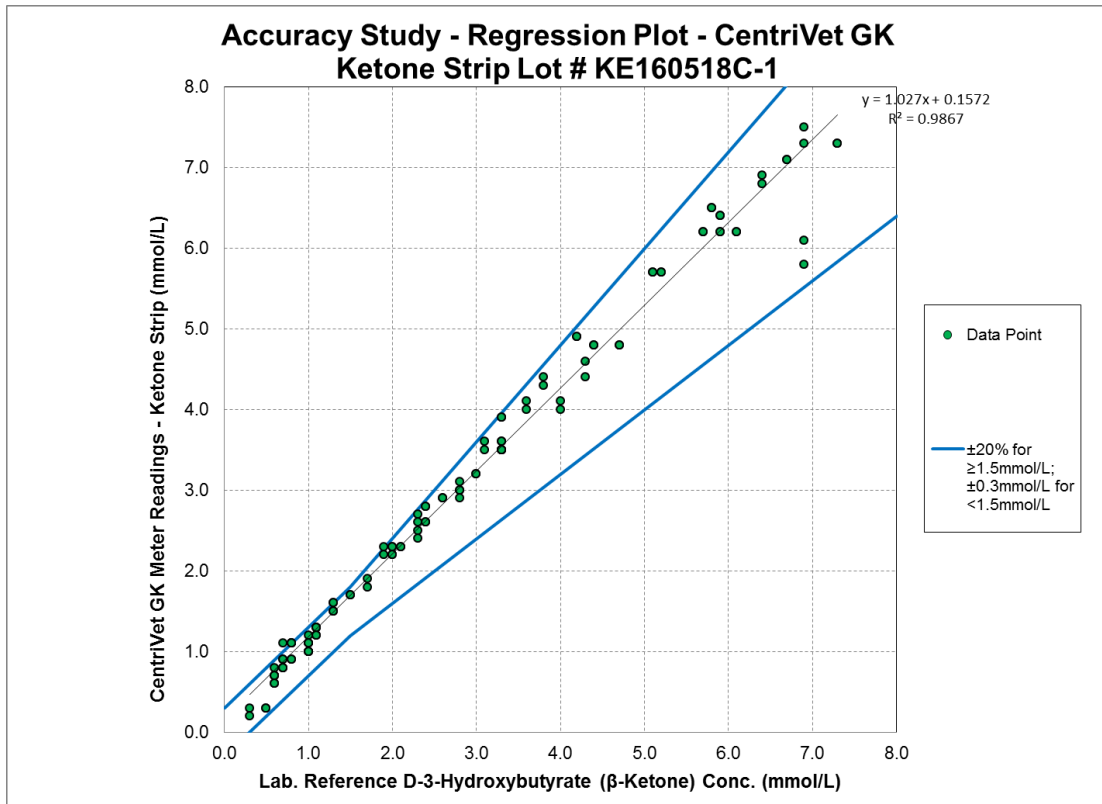
4.0 Results

Data Analysis:

Regression Analysis

Accuracy test results are also analyzed by using “regression analysis”.

CentriVet Blood Glucose and Ketone Meter Reading – CentriVet Blood Ketone Strip vs. Laboratory Reference Method, Canine Whole Blood Sample: Strip Lot KE160518C-1



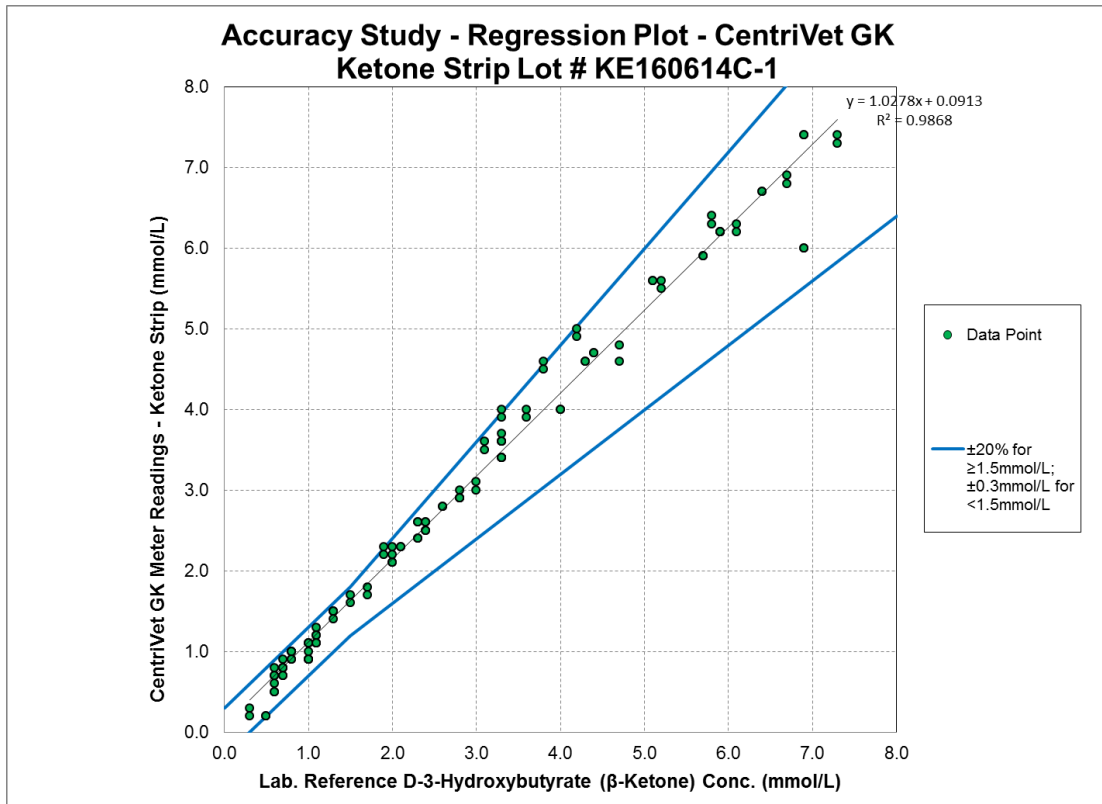
N = 118

Slope = 1.027

Intercept = 0.1572

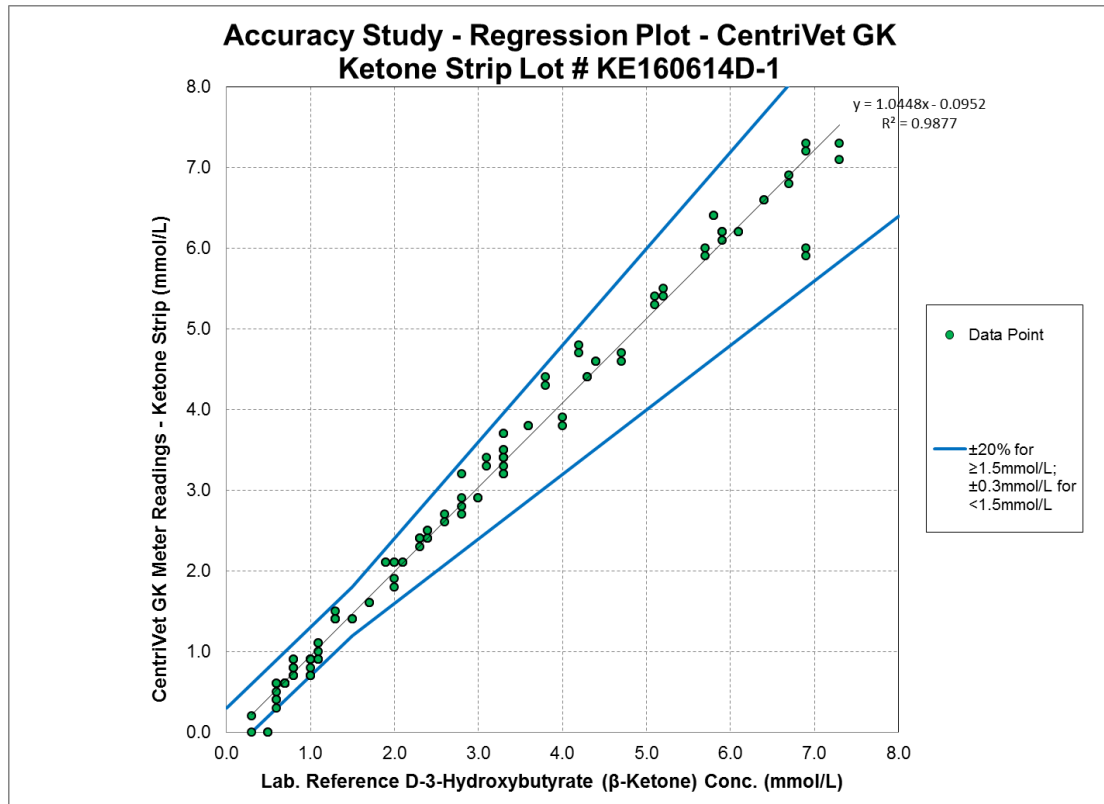
$R^2 = 0.9867$

CentriVet Blood Glucose and Ketone Meter Reading – CentriVet Blood Ketone Strip vs. Laboratory Reference Method, Canine Whole Blood Sample: Strip Lot KE160614C-1



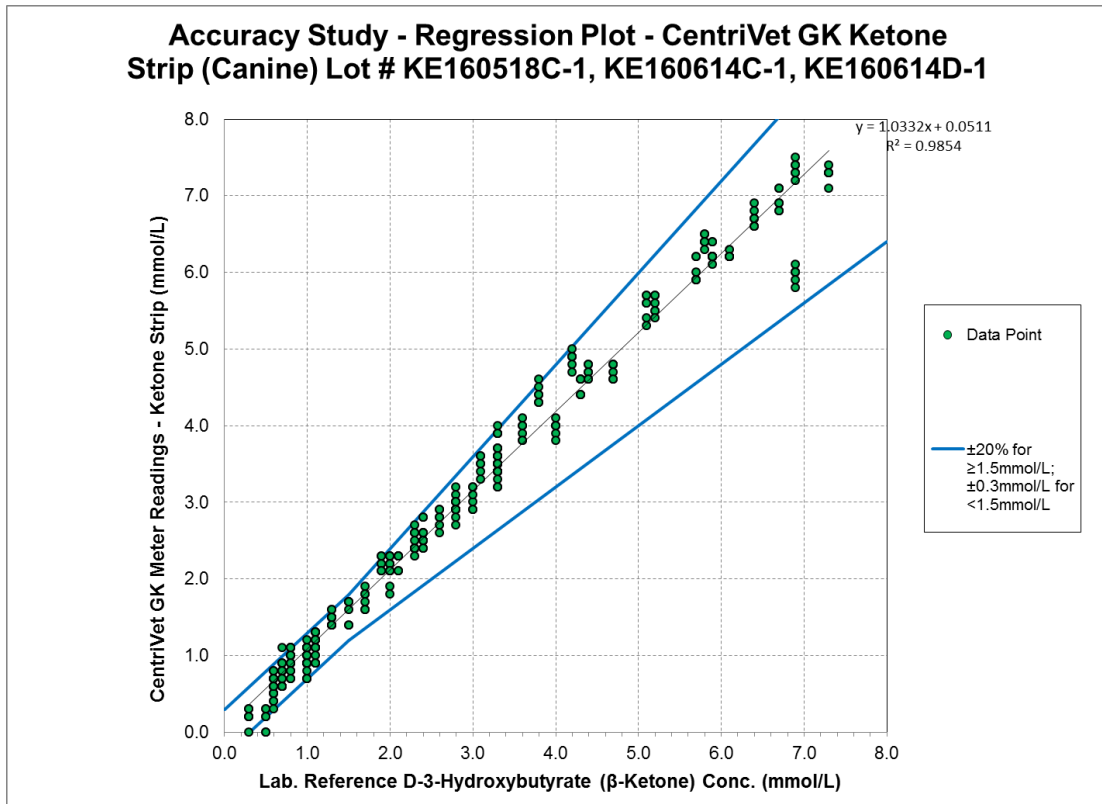
N = 118
Slope = 1.0278
Intercept = 0.0913
 $R^2 = 0.9868$

CentriVet Blood Glucose and Ketone Meter Reading – CentriVet Blood Ketone Strip vs. Laboratory Reference Method, Canine Whole Blood Sample: Strip Lot KE160614D-1



N = 118
Slope = 1.0448
Intercept = -0.0952
 $R^2 = 0.9877$

CentriVet Blood Glucose and Ketone Meter Reading – CentriVet Blood Ketone Strip vs. Laboratory Reference Method, Canine Whole Blood Sample: All 3 Strip Lots KE160518C-1, KE160614C-1, and KE160614D-1 Combined



N = 354

Slope = 1.0332

Intercept = 0.0511

$R^2 = 0.9854$

Data Table

System Accuracy Results of CentriVet Blood Glucose and Ketone Monitoring System – CentriVet Blood Ketone Strip, Canine Whole Blood Sample for each strip lot:

CentriVet GK Monitoring System - Ketone Strip, Canine Blood Sample			
Strip Lot: KE160518C-1			
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
11 / 78 (14.1%)	48 / 78 (61.5%)	66 / 78 (84.6%)	77 / 78 (98.7%)
System Accuracy Results for D-3-Hydroxybutyrate Concentration < 1.5 mmol/L			
Within ± 0.1 mmol/L	Within ± 0.2 mmol/L	Within ± 0.3 mmol/L	
21 / 40 (52.5%)	33 / 40 (82.5%)	39 / 40 (97.5%)	
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L and < 1.5 mmol/L			
Within $\pm 15\%$ or ± 0.3 mmol/L		Within $\pm 20\%$ or ± 0.3 mmol/L	
105 / 118 (89.0%)		116 / 118 (98.3%)	

CentriVet GK Monitoring System - Ketone Strip, Canine Blood Sample			
Strip Lot: KE160614C-1			
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
30 / 78 (38.5%)	59 / 78 (75.6%)	69 / 78 (88.5%)	75 / 78 (96.2%)
System Accuracy Results for D-3-Hydroxybutyrate Concentration < 1.5 mmol/L			
Within ± 0.1 mmol/L	Within ± 0.2 mmol/L	Within ± 0.3 mmol/L	
28 / 40 (70.0%)	38 / 40 (95.0%)	40 / 40 (100.0%)	
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L and < 1.5 mmol/L			
Within $\pm 15\%$ or ± 0.3 mmol/L		Within $\pm 20\%$ or ± 0.3 mmol/L	
109 / 118 (92.4%)		115 / 118 (97.5%)	

CentriVet GK Monitoring System - Ketone Strip, Canine Blood Sample			
Strip Lot: KE160614D-1			
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
47 / 78 (60.3%)	65 / 78 (83.3%)	77 / 78 (98.7%)	78 / 78 (100.0%)
System Accuracy Results for D-3-Hydroxybutyrate Concentration < 1.5 mmol/L			
Within ± 0.1 mmol/L	Within ± 0.2 mmol/L	Within ± 0.3 mmol/L	
26 / 40 (65.0%)	33 / 40 (82.5%)	38 / 40 (95.0%)	
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L and < 1.5 mmol/L			
Within $\pm 15\%$ or ± 0.3 mmol/L		Within $\pm 20\%$ or ± 0.3 mmol/L	
115 / 118 (97.5%)		116 / 118 (98.3%)	

System Accuracy Results of CentriVet Blood Glucose and Ketone Monitoring System – Blood Ketone Strip, Canine Whole Blood Sample for all 3 lots combined:

CentriVet GK Monitoring System - Ketone Strip, Canine Blood Sample			
Strip Lots: KE160518C-1, KE160614C-1, KE160614D-1			
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
88 / 234 (37.6%)	172 / 234 (73.5%)	212 / 234 (90.6%)	230 / 234 (98.3%)
System Accuracy Results for D-3-Hydroxybutyrate Concentration < 1.5 mmol/L			
Within ± 0.1 mmol/L	Within ± 0.2 mmol/L	Within ± 0.3 mmol/L	
75 / 120 (62.5%)	104 / 120 (86.7%)	117 / 120 (97.5%)	
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L and < 1.5 mmol/L			
Within $\pm 15\%$ or ± 0.3 mmol/L		Within $\pm 20\%$ or ± 0.3 mmol/L	
329 / 354 (92.9%)		347 / 354 (98.0%)	

5.0 Conclusion

The results showed that more than 95% of data points for all 3 lots of CentriVet Blood Ketone Strip, with CentriVet Blood Glucose and Ketone Monitoring System, for canine whole blood sample were within $\pm 20\%$ versus laboratory reference values when D-3-hydroxybutyrate (β -ketone) concentration is $\geq 1.5\text{mmol/L}$, or within $\pm 0.3\text{mmol/L}$ versus laboratory reference values when D-3-hydroxybutyrate concentration is $< 1.5\text{mmol/L}$. This indicates the system accuracy results for meet the acceptance criteria.