



CentriVet Blood Glucose and Ketone Monitoring System

CentriVet Blood Ketone Strip Feline Whole Blood Sample

Accuracy Study Report

Azure Institute
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	Department	Signature	Date
Originator	G-strip R&D	Yulan Sun	2016.10.28
Reviewer	G-strip R&D	Allen Wang	2016.10.28
Approval	G-strip R&D	Hui-wu 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 feline whole blood samples, when compared to a laboratory reference measurement method, meets the accuracy acceptance criteria.

2.0 Methods

Feline 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, feline 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 feline blood samples were drawn from 15 individual felines.

Sample Type:

Feline 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 0.1 to 7.8 mmol/L

The subject blood hematocrit range is from 19% to 55%.

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 feline 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 feline blood samples were drawn from adult cats 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.

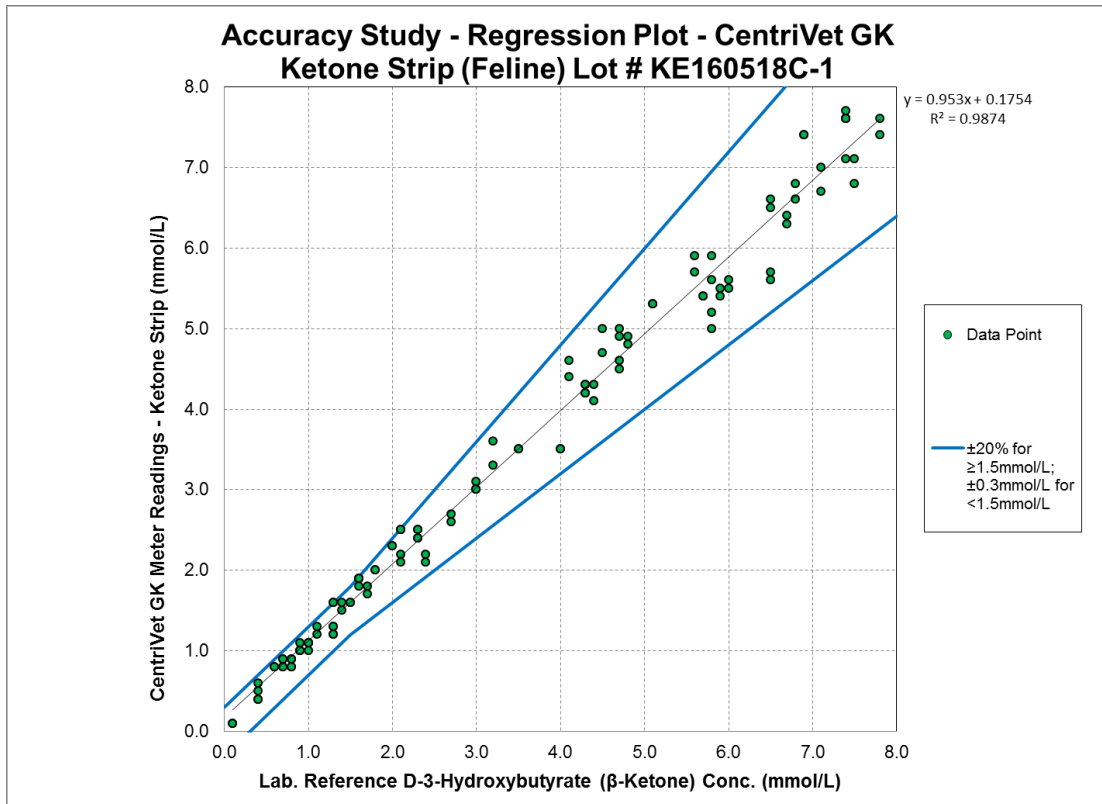
4.0 Results

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, Feline Whole Blood Sample: Strip Lot KE160518C-1



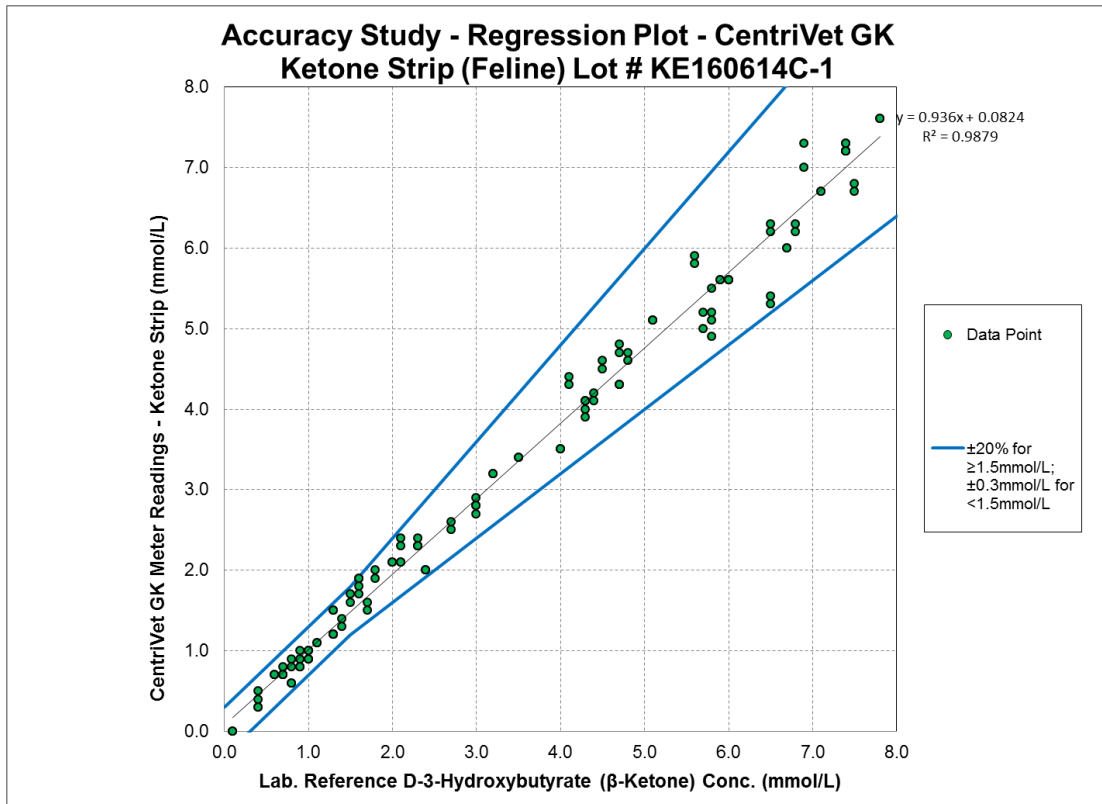
N = 120

Slope = 0.9530

Intercept = 0.1754

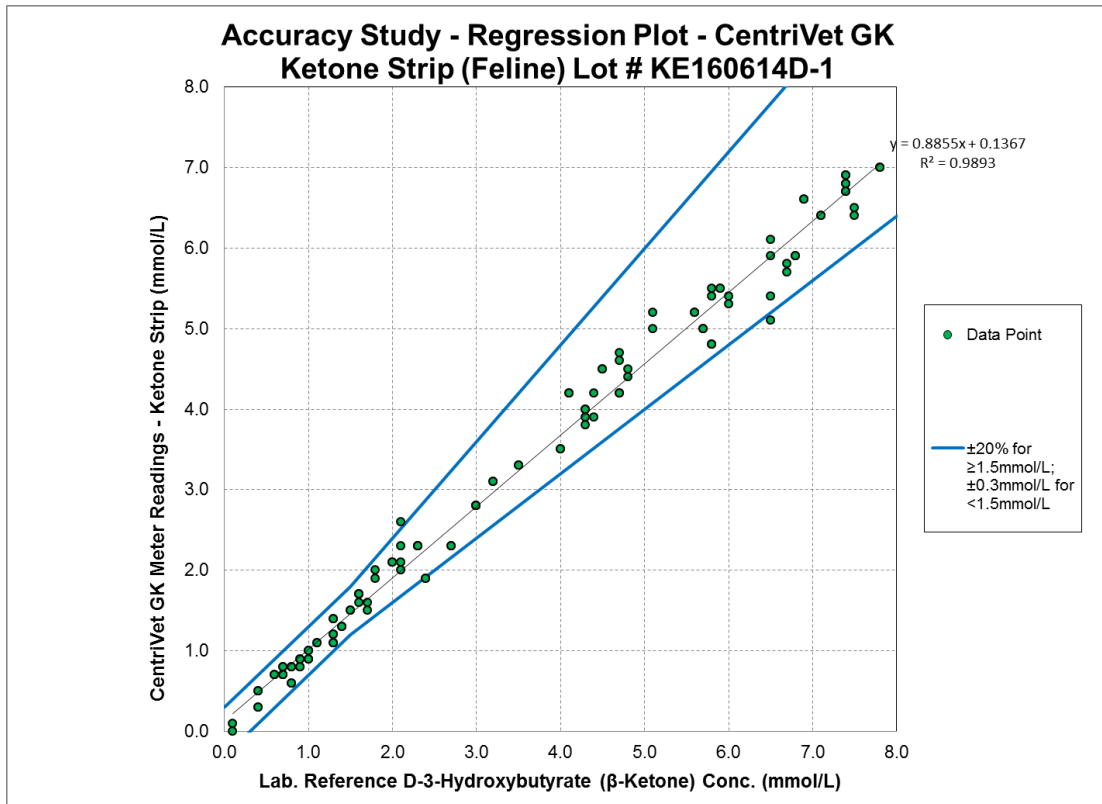
$R^2 = 0.9874$

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



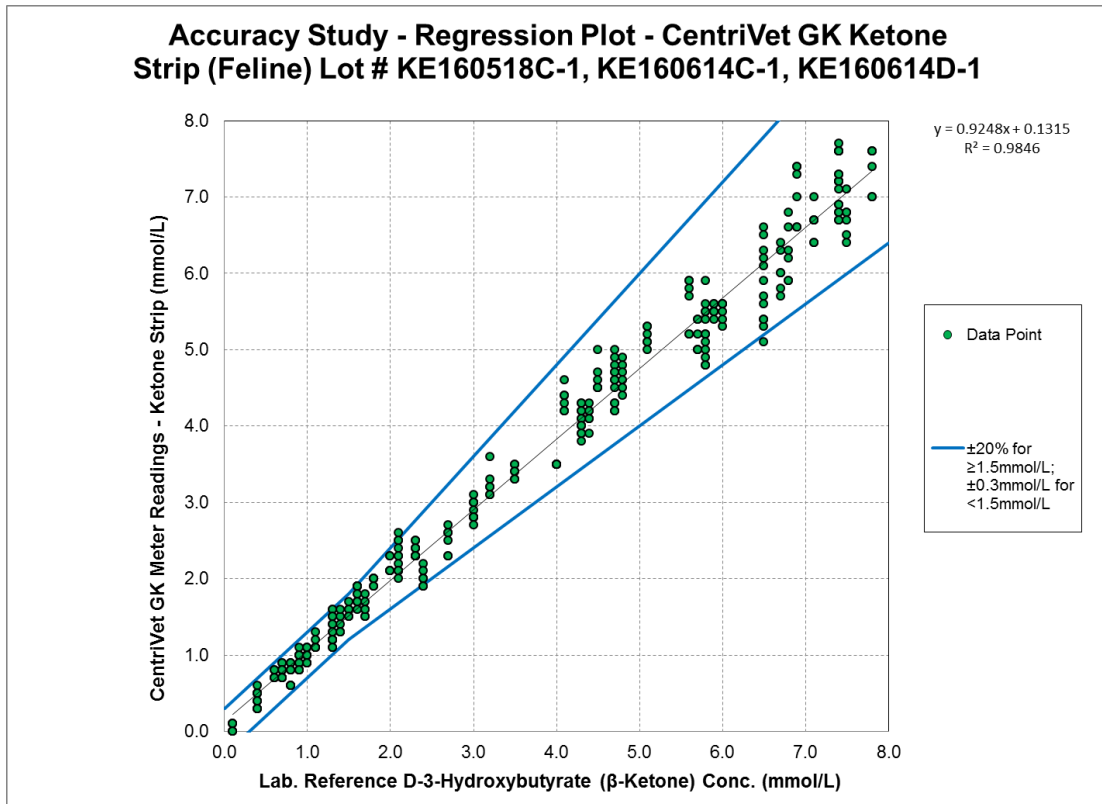
N = 120
Slope = 0.936
Intercept = 0.0824
 $R^2 = 0.9879$

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



N = 120
Slope = 0.8855
Intercept = 0.1367
 $R^2 = 0.9893$

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



N = 360
Slope = 0.9248
Intercept = 0.1315
 $R^2 = 0.9846$

Data Table

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

CentriVet GK Monitoring System - Ketone Strip, Feline Whole 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 $\pm 20\%$
43 / 86 (50.0%)	66 / 86 (76.7%)	81 / 86 (94.2%)	86 / 86 (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	
24 / 34 (70.6%)	32 / 34 (94.1%)	34 / 34 (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	
115 / 120 (95.8%)		120 / 120 (100.0%)	

CentriVet GK Monitoring System - Ketone Strip, Feline Whole 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 $\pm 20\%$
38 / 86 (44.2%)	66 / 86 (76.7%)	79 / 86 (91.9%)	86 / 86 (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	
30 / 34 (88.2%)	34 / 34 (100.0%)	34 / 34 (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	
113 / 120 (94.2%)		120 / 120 (100.0%)	

CentriVet GK Monitoring System - Ketone Strip, Feline Whole 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 $\pm 20\%$
24 / 86 (27.9%)	58 / 86 (67.4%)	79 / 86 (91.9%)	82 / 86 (95.3%)
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	
30 / 34 (88.2%)	34 / 34 (100.0%)	34 / 34 (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	
113 / 120 (94.2%)		116 / 120 (96.7%)	

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

CentriVet GK Monitoring System - Ketone Strip, Feline Whole 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 $\pm 20\%$
105 / 258 (40.7%)	190 / 258 (73.6%)	239 / 258 (92.6%)	254 / 258 (98.4%)
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	
84 / 102 (82.4%)	100 / 102 (98.0%)	102 / 102 (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	
341 / 360 (94.7%)		356 / 360 (98.9%)	

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 feline 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.