



CentriVet Blood Glucose and Ketone Monitoring System

CentriVet Blood Glucose Strip Canine Whole Blood Sample

Accuracy Study Report

Azure Institute
Oct 2022

	Department	Signature	Date
Originator	G Strip R&D	Leila Ye	Oct 9, 2022
Reviewer	G strip R&D	Quinn Tomy	Oct 9, 2022
Approval	G Strip R&D	Alice Sun	Oct 9, 2022

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 Glucose 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 glucose was measured with a reference method and CentriVet Blood Glucose and Ketone Monitoring System with CentriVet Blood Glucose Strip for comparison. Additionally, canine whole blood samples were spiked with additional glucose to obtain samples with high concentration of glucose.

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:

YSI 2300 STAT Plus

Tested Glucose Concentration Range:

The tested glucose concentration range is from 47.3 mg/dL to 603 mg/dL

The subject blood hematocrit range is from 34% to 49%.

Number of Strip Lots and Meters:

3 strip lots were tested for the study. Strip lot E160224E-1, E160524E-1 and E160604E-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 whole blood sample with CentriVet Blood Glucose 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

A) 95 % of the measured glucose values shall fall within either ± 15 mg/dL of the average measured values of the reference measurement procedure at glucose concentrations < 100 mg/dL or within $\pm 15\%$ at glucose concentrations ≥ 100 mg/dL.

B) 99 % of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid (CEG).

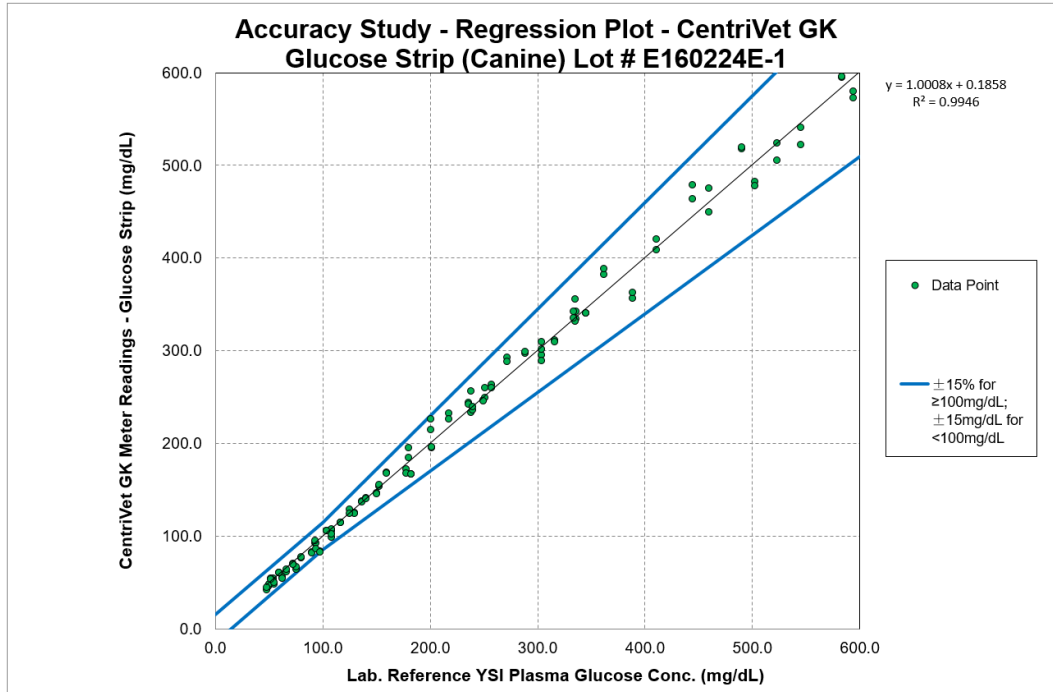
4.0 Results

Data Analysis:

Regression Analysis

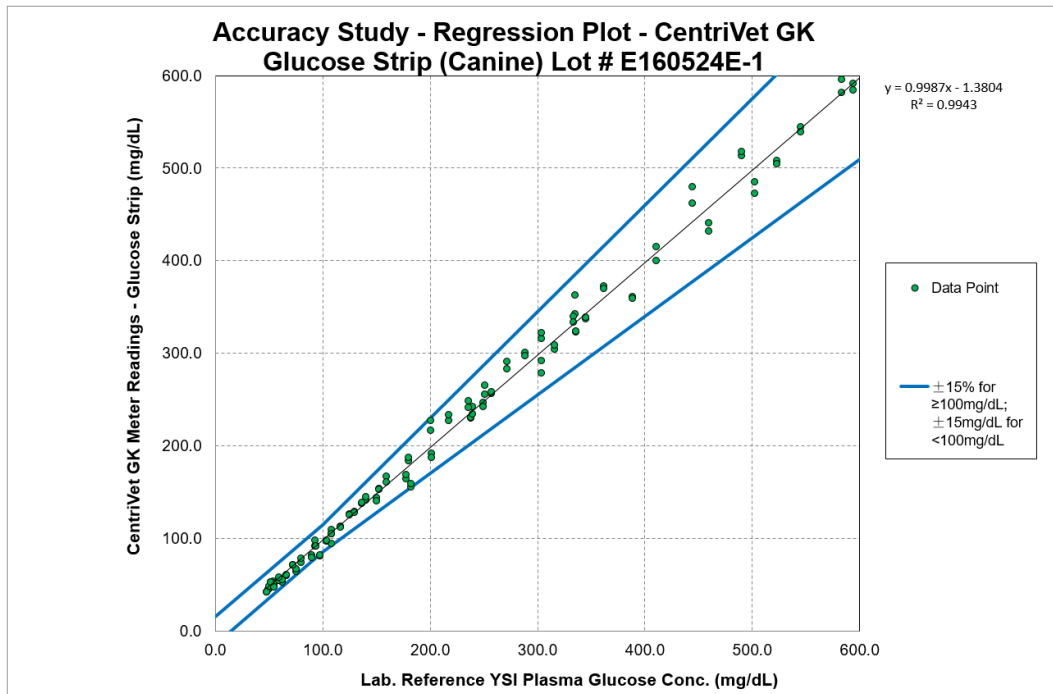
Accuracy test results are also analyzed by using “regression analysis”.

CentriVet Blood Glucose and Ketone Meter Reading – CentriVet Blood Glucose Strip vs. Laboratory Reference Method, Canine Whole Blood Sample: Strip Lot E160224E-1



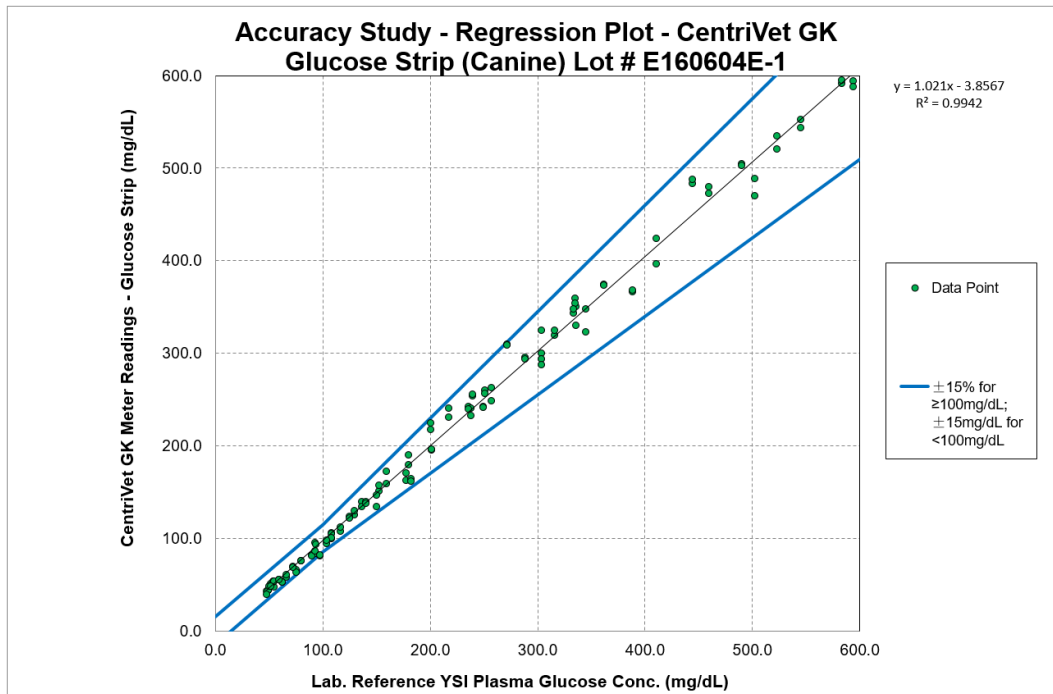
N = 120
Slope = 1.0008
Intercept = 0.1858
 $R^2 = 0.9946$

CentriVet Blood Glucose and Ketone Meter Reading – CentriVet Blood Glucose Strip vs. Laboratory Reference Method, Canine Whole Blood Sample: Strip Lot E160524E-1



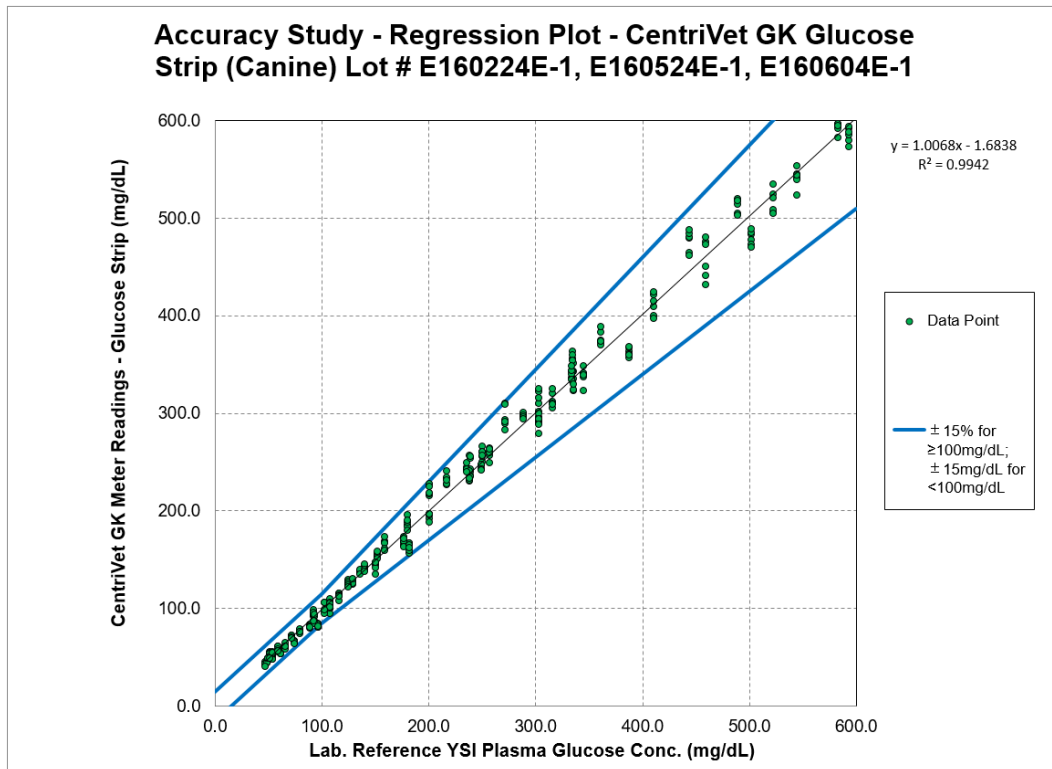
N = 120
Slope = 0.9987
Intercept = -1.3804
 $R^2 = 0.9943$

CentriVet Blood Glucose and Ketone Meter Reading – CentriVet Blood Glucose Strip vs. Laboratory Reference Method, Canine Whole Blood Sample: Strip Lot E160604E-1



N = 120
Slope = 1.021
Intercept = -3.8567
 $R^2 = 0.9942$

CentriVet Blood Glucose and Ketone Meter Reading – CentriVet Blood Glucose Strip vs. Laboratory Reference Method, Canine Whole Blood Sample: All 3 Strip Lots E160224E-1, E160524E-1 and E160604E-1 Combined



N=360
Slope = 1.0068
Intercept = -1.6838
 $R^2=0.9942$

Data Table

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

CentriVet GK Monitoring System - Glucose Strip, Canine Blood Sample		
Strip Lot E160224E-1		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
66 / 88 (75.0%)	87 / 88 (98.9%)	88 / 88 (100.0%)
System Accuracy Results for Glucose Concentration < 100 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
22 / 32 (68.8%)	30 / 32 (93.8%)	32 / 32 (100.0%)
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within $\pm 15\%$ or ± 15 mg/dL		
120 / 120 (100.0%)		

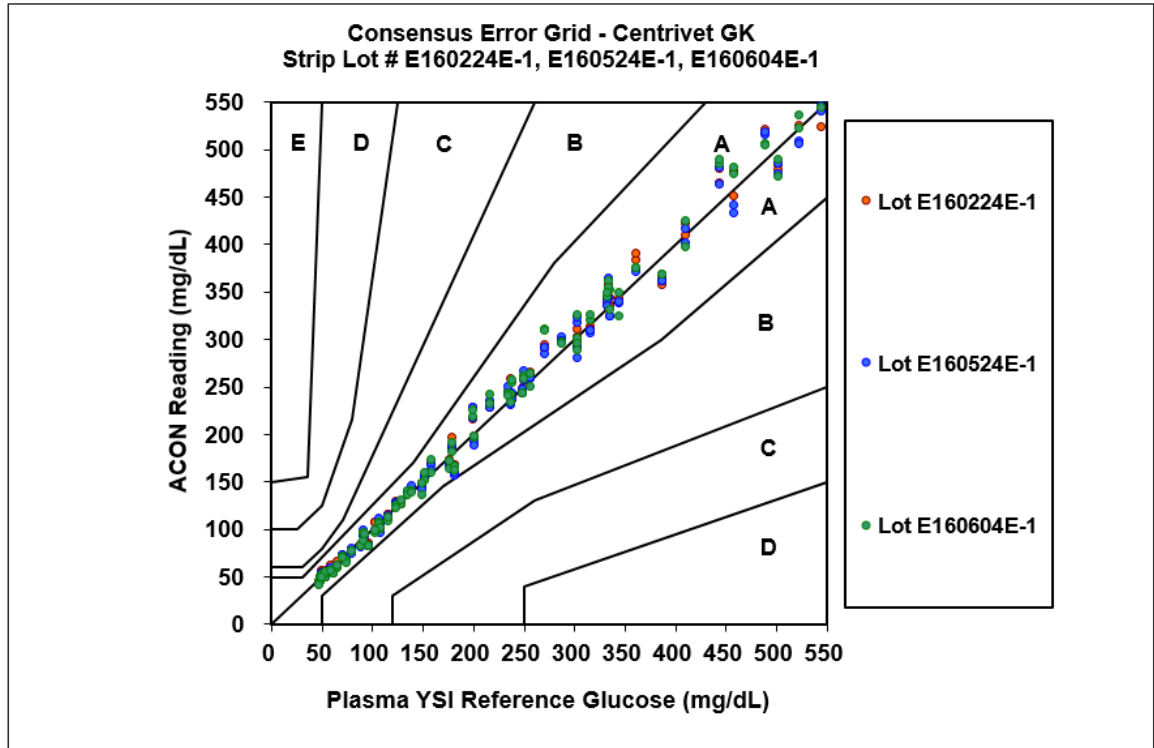
CentriVet GK Monitoring System - Glucose Strip, Canine Blood Sample		
Strip Lot E160524E-1		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
63 / 88 (71.6%)	84 / 88 (95.5%)	88 / 88 (100.0%)
System Accuracy Results for Glucose Concentration < 100 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
18 / 32 (56.3%)	30 / 32 (93.8%)	31 / 32 (96.9%)
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within $\pm 15\%$ or ± 15 mg/dL		
119 / 120 (99.2%)		

CentriVet GK Monitoring System - Glucose Strip, Canine Blood Sample		
Strip Lot: E160604E-1		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
60 / 88 (68.2%)	83 / 88 (94.3%)	88 / 88 (100.0%)
System Accuracy Results for Glucose Concentration < 100 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
19 / 32 (59.4%)	29 / 32 (90.6%)	31 / 32 (96.9%)
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within $\pm 15\%$ or ± 15 mg/dL		
119 / 120 (99.2%)		

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

CentriVet GK Monitoring System - Glucose Strip, Canine Blood Sample		
Strip Lots: E160224E-1, E160524E-1, E160604E-1		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
189 / 264 (71.6%)	254 / 264 (96.2%)	264 / 264 (100.0%)
System Accuracy Results for Glucose Concentration < 100 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
59 / 96 (61.5%)	89 / 96 (92.7%)	94 / 96 (97.9%)
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within $\pm 15\%$ or ± 15 mg/dL		
358 / 360 (99.4%)		

Consensus Error Grid Analysis



Accuracy Study - Arterial by Technician							
Consensus Error Bird	Strip Lot	Zone A	Zone B	Zone C	Zone D	Zone E	Total
No.of Data Point	E160224E-1	120	0	0	0	0	120
No.of Data Point	E160524E-1	120	0	0	0	0	120
No.of Data Point	E160604E-1	120	0	0	0	0	120

From the analysis of Consensus Error Grid analysis, the results showed that more than 99% of data points were within Zone A and B. This indicates the system accuracy results for clinical study meet the Acceptance Criteria B.

5.0 Conclusion

The results showed that more than 95% of data points for all 3 lots of CentriVet Glucose Strip, with CentriVet Glucose and Ketone Monitoring System, for canine whole blood sample, were within $\pm 15\%$ versus laboratory reference values when glucose concentration is $\geq 100\text{mg/dL}$, or within $\pm 15\text{mg/dL}$ versus laboratory reference values when glucose concentration is $< 100\text{mg/dL}$. This indicates the system accuracy results for CentriVet Glucose and Ketone Monitoring System – CentriVet Glucose Strip meet the Acceptance Criteria A.

From the analysis of Consensus Error Grid analysis, the results showed that more than 99% of data points were within Zone A and B. This indicates the system accuracy results meet the Acceptance Criteria B.