CentriVet Blood Glucose and Ketone Monitoring System

Bovine Blood – CentriVet Blood Ketone Strip

Accuracy Study Report

Nov 2015

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 bovine blood samples, when compared to a laboratory reference measurement method, meets the accuracy acceptance criteria.

2.0 Methods

Bovine blood samples from lactating cows were obtained. 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, bovine blood samples were further spiked with D-3-hydroxybutyrate (β-ketone) to obtain bovine blood samples with high concentration of D-3-hydroxybutyrate (β-ketone).

Study Site:
The clinical study was conducted at AZURE Institute, San Diego, California, USA.

Sample Type:
Venous bovine blood sample was drawn from the tail vein of the subject with a syringe and needle and injected into a blood collection tube with heparin anticoagulant.

Reference Method:
Procedures were followed according to instructions given in Randox D-3-Hydroxybutyrate (Ranbut) assay kit package insert to prepare samples. Measurements were taken using Genesys UV-Vis Spectrophotometer.

Number of Strip Lots and Meters:
3 strip lots and 6 meters were tested for the study. The meters reported plasma equivalent blood β-ketone concentration values.

Code Chips:
Bovine code chips are specific for bovine blood sample with CentriVet Blood Ketone Strips.

3.0 Acceptance Criteria

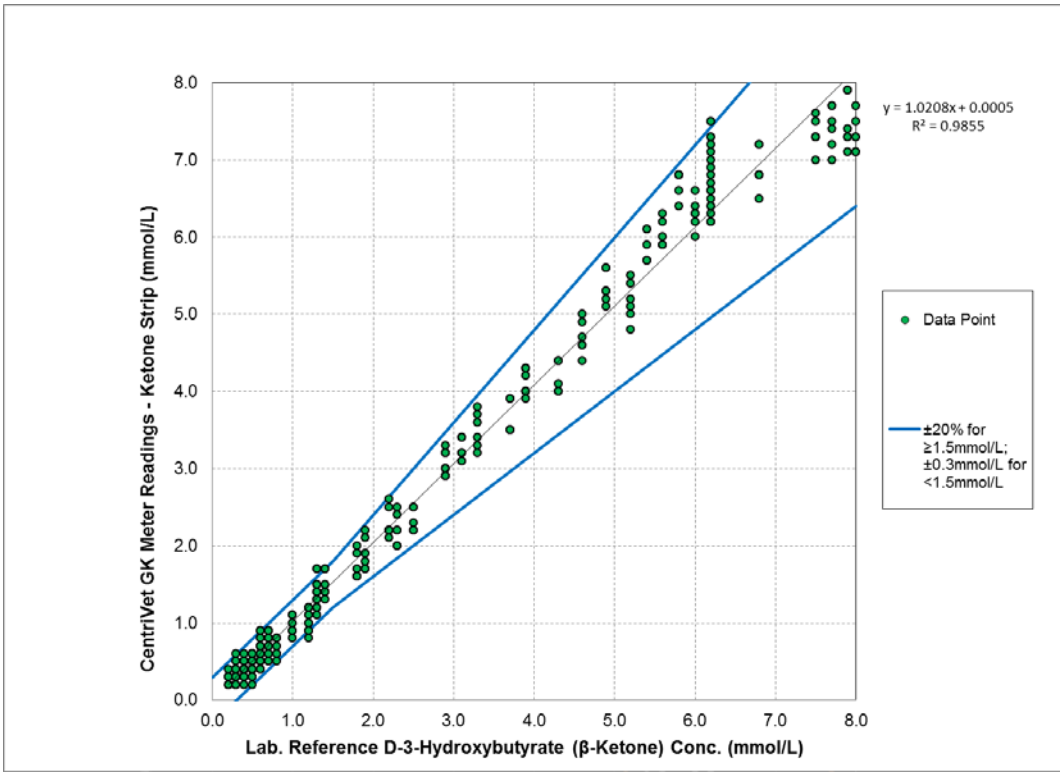
95 % of the measured values shall fall within either ±0.3mmol/L of the average measured values of the reference measurement at D-3-hydroxybutyrate (β-ketone) concentrations <1.5mmo/L or within ±20% of the average measured values of the

reference measurement at D-3-hydroxybutyrate (β-ketone) concentrations ≥1.5mmol/L.

4.0 Results

Regression Analysis

CentriVet Blood Glucose and Ketone Meter Reading – CentriVet Blood Ketone Strip vs. Laboratory Reference Method, Bovine Blood Sample: All 3 Strip Lots Combined



N = 336
Slope = 1.0208
Intercept = 0.0005
R^2 = 0.9855

Data Table

System Accuracy Results of CentriVet Blood Glucose and Ketone Monitoring System – Blood Ketone Strip, Bovine Blood Sample, for All 3 Lots Combined:

CentriVet GK Monitoring System - Ketone Strip, Bovine Blood Sample			
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥1.5 mmol/L			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
66 / 162 (40.7%)	116 / 162 (71.6%)	150 / 162 (92.6%)	160 / 162 (98.8%)
System Accuracy Results for D-3-Hydroxybutyrate Concentration <1.5 mmol/L			
Within ±0.1mmol/L	Within ±0.2mmol/L	Within ±0.3mmol/L	
135 / 174 (77.6%)	161 / 174 (92.5%)	171 / 174 (98.3%)	
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥1.5 mmol/L and <1.5 mmol/L			
Within ±15% or ±0.3mmol/L		Within ±20% or ±0.3mmol/L	
321 / 336 (95.5%)		331 / 336 (98.5%)	

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 bovine blood sample were within ±20% versus laboratory reference values when D-3-hydroxybutyrate (β-ketone) concentration is ≥1.5mmol/L, or within ±0.3mmol/L versus laboratory reference values when D-3-hydroxybutyrate concentration is <1.5mmol/L. The system accuracy results meet the acceptance criteria.