

**CentriVet Blood Glucose and  
Ketone  
Monitoring System**

**Bovine Blood – CentriVet Blood  
Glucose Strip**

**Accuracy Study Report**

**Feb 2016**

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

### **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:**

Reference instrument is YSI 2300 STAT Plus. Reference values of glucose concentration were measured using plasma samples prepared from bovine whole blood samples.

### **Number of Strip Lots and Meters:**

3 strip lots and 6 meters were tested for the study. The meters reported plasma equivalent blood glucose concentration values.

### **Code Chips:**

Bovine code chips are specific for bovine blood sample with CentriVet Blood Glucose Strips.

## **3.0 Acceptance Criteria**

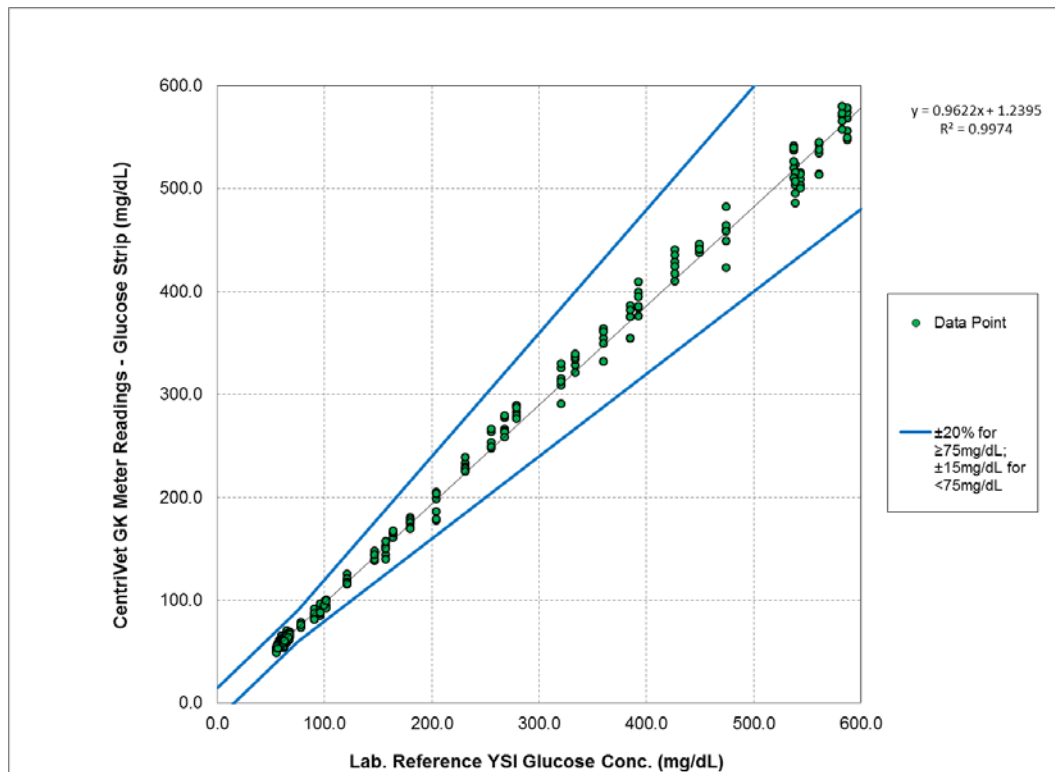
95 % of the measured values shall fall within either  $\pm 15\text{mg/dL}$  of the average measured values of the reference measurement at glucose concentrations  $< 75\text{mg/dL}$

or within  $\pm 20\%$  of the average measured values of the reference measurement at glucose concentrations  $\geq 75\text{mg/dL}$ .

## 4.0 Results

### Regression Analysis

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



N=360

Slope = 0.9622

Intercept = 1.2395

$R^2=0.9974$

## Data Table

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

<b>CentriVet GK Monitoring System - Glucose Strip, Bovine Blood Sample</b>			
System Accuracy Results for Glucose Concentration $\geq 75$ mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
134 / 180 ( 74.4% )	173 / 180 ( 96.1% )	180 / 180 ( 100.0% )	180 / 180 ( 100.0% )
System Accuracy Results for Glucose Concentration $< 75$ mg/dL			
Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL	
163 / 180 ( 90.6% )	180 / 180 ( 100.0% )	180 / 180 ( 100.0% )	
System Accuracy Results for Glucose Concentration $\geq 75$ mg/dL and $< 75$ mg/dL			
Within $\pm 15\%$ or $\pm 15$ mg/dL		Within $\pm 20\%$ or $\pm 15$ mg/dL	
360 / 360 ( 100.0% )		360 / 360 ( 100.0% )	

## **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 bovine blood sample were within  $\pm 20\%$  versus laboratory reference values when glucose concentration is  $\geq 75$ mg/dL, or within  $\pm 15$ mg/dL versus laboratory reference values when glucose concentration is  $< 75$ mg/dL. The system accuracy results meet the acceptance criteria.