CLINICAL ACCURACY
AND PERFORMANCE OF

TEST BUDDY™

PET-MONITORING
BLOOD GLUCOSE SYSTEM

TRIVIDIA HEALTH™

Summary

Objective: The prevalence of diabetes among canines and felines has increased in recent years. According to American Animal Hospital Association guidelines, human blood glucose monitoring systems are not recommended for use with canines and felines. The Test Buddy™ Pet-Monitoring Blood Glucose System is designed and calibrated for canines and felines, with convenient, easy-to-use features such as Bluetooth® compatibility and simple, 2-step testing. The objective of this study was to evaluate the performance of the Test Buddy™ Pet-Monitoring Blood Glucose System in canines and felines, including clinical performance validation, system precision, interference testing, and ease of use. The clinical accuracy of the Test Buddy™ System was also compared to that of a leading competitor.

Methods: This study enrolled canine and feline subjects. Subjects provided fresh capillary (drawn from the paw pad and/or the ear) and venous blood samples. A trained technician performed reference, Test Buddy™, and leading competitor assays. Results from canine and feline subjects are presented using bias plots and bias tables for capillary, venous, and cumulative (capillary + venous combined) data. The acceptance measure is the percentage of results from the Test Buddy™ System within the accuracy acceptance criteria listed in EN ISO 15197:2003 compared to a leading competitor.

Results: Among 113 canine subjects, a total of 86.3% capillary paw pad, 87.9% capillary ear, and 98.8% venous results using the Test Buddy™ System were within the specified acceptance criteria. Pooled data from capillary paw pad, capillary ear, and venous samples demonstrate that more canine Test Buddy™ System samples (95.0%) were within ±15 mg/dL or ±20% of the reference sample than for a leading competitor (83.1%). Among 114 feline subjects, a total of 91.7% capillary paw pad, 93.4% capillary ear, and 97.9% venous results using the Test Buddy™ System were within the specified acceptance criteria. Pooled data from capillary paw pad, capillary ear, and venous samples demonstrate that more feline Test Buddy™ System samples (96.0%) were within ±15 mg/dL or ±20% of the reference sample than for a leading competitor (73.6%). Interference testing indicates that the ingestion of supplements containing Vitamin C, the use of a "short draw" with EDTA in which the vacutainer tube is less than half full, or the presence of >16% hemolysis may cause interference with glucose test results.

Conclusion: The Test Buddy™ Pet-Monitoring Blood Glucose System from Trividia Health demonstrates proven precision, accuracy, and ease of use when measuring blood glucose in canines and felines, and has proven to be more accurate than a leading competitor.

Introduction

Given the substantial increase in the prevalence of diabetes among dogs (canines) and cats (felines) in recent years,[1] daily blood glucose monitoring has become a common task for many pet owners. Hematocrit affects the accuracy of blood glucose determinations for animals and humans differently. Monitoring systems are designed to operate within a specific range of hematocrit values,[2] so human blood glucose monitoring systems are not recommended for canine and feline blood glucose monitoring.[3]

Normal hematocrit ranges differ between species, ranging from 38% to 49% in humans,[4] 36% to 60% in canines,[5] and 29% to 48% in felines.[5] Target glucose values also vary between species; according to the American Animal Hospital Association, the target range for canines and felines is 80 to 150 mg/dL,[3] whereas the target glucose range recommended by the American Diabetes Association for humans is 80 to 130 mg/dL.[6] In addition, species-specific differences in glucose distribution between red blood cells and plasma[7] further affect the performance of blood glucose monitoring systems across species. Canine and feline blood glucose concentrations measured using human blood glucose monitoring systems are often lower than those measured using standard reference methods,[8,9] potentially leading to inaccurate results. The use of species-specific blood glucose meters with species-appropriate calibration improves the accuracy of the results due to differences in the distribution of glucose,[7] the composition of the blood (the percentage of red blood cells), and the size of the red blood cells.

The Test Buddy™ Pet-Monitoring Blood Glucose System is specially designed and calibrated for canines and felines, with convenient, easy-to-use features such as Bluetooth® compatibility and simple, 2-step testing (**Table 1**). The advanced system was developed with a specific chemistry and a unique algorithm; the Test Buddy™ System is tailored to the specific hematocrit ranges and glucose distributions of canine and feline blood samples (**Figure 1**).

The Test Buddy™ App wirelessly receives results from the Test Buddy™ Pet-Monitoring Blood Glucose Meter to enable tracking of the pet's glucose results on a mobile device. A digital logbook shows the date, time, blood glucose result, and event tag from the meter, and each blood glucose result is color coded to indicate if the canine or feline is within his or her acceptable range (**Figure 2**). The data can be shared with veterinarians to help manage the diabetes treatment plan remotely. The App is intended to support diabetes management without providing specific treatment or treatment suggestions. A veterinarian must be consulted for treatment plan changes. The Test Buddy™ App is available on both Android and iOS operating systems.

For more information about the importance of
monitoring pet glucose levels at home

Click here

healthy-tracks.com/vet-blog

Table 1. Summary of Test Buddy™ Performance Criteria

Features	Performance
Coding	No coding
Blood volume	0.5 µL
Testing time	About 10 seconds
Sample types	Fresh capillary whole blood, venous whole blood collected in an EDTA blood collection tube, or control solution
Sample sites	Paw pad, ear, and venous
Enzyme	GDH-FAD
Control detection	Automatic detection
Fill detection	Audible indication
Test strip release	No handling of used test strips
Blood glucose range	20-600 mg/dL
Hematocrit range	20%-60%
Altitude range	Up to 10,150 ft
Operating temperature range	50°F-104°F
Test memory	1,000 tests
Test averaging	7, 14, 30, 60, and 90-day
Time/date tracking	Both time and date
Event tagging	4 event tags (exercise, before meal, partial meal, and after meal)
Data management	Bluetooth® SMART

GDH-FAD, glucose dehydrogenase-FAD (*Aspergillus species*).

Figure 1. Key Features of Test Buddy™

Animal Selection
Toggle between settings for canines and felines

Sample Types
Appropriate for capillary paw pad, capillary ear, and venous testing

Hematocrit Range
Functions within hematocrit range 20%-60%

Event Tags
Advanced event tags combine pet activities with results
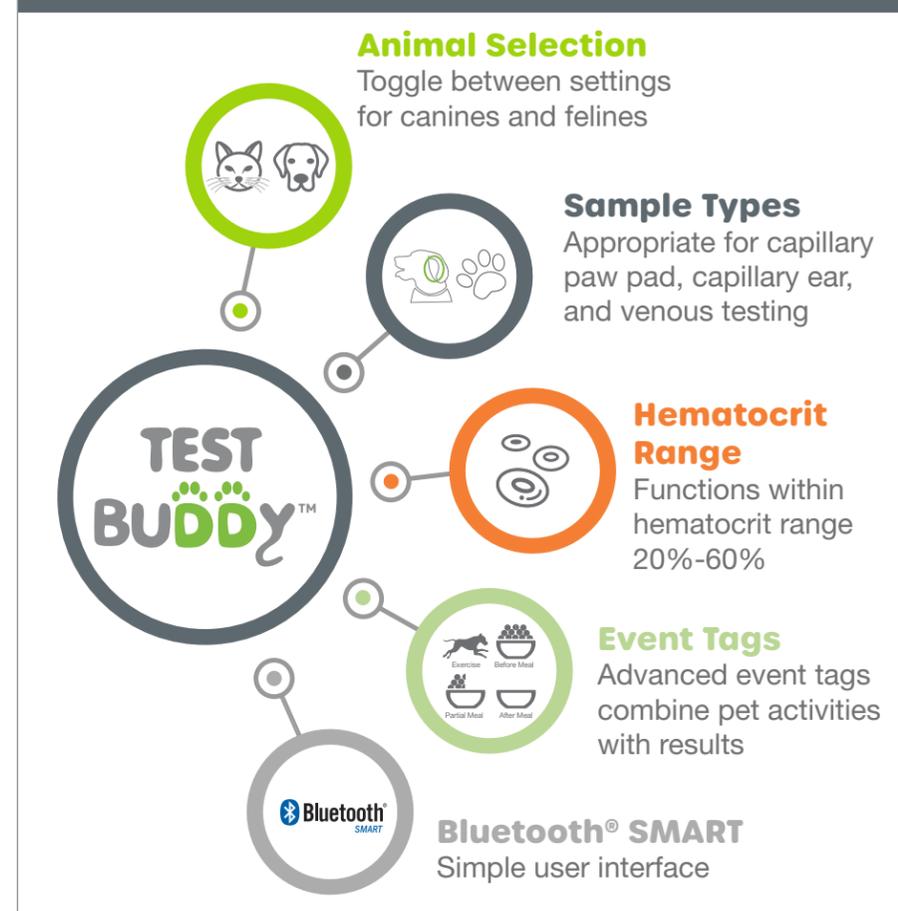
Bluetooth® SMART
Simple user interface

Figure 2. Screenshots of the Test Buddy™ App for iOS Users

Screenshots of the App for iOS users are shown as examples; Android screens may look slightly different.

Test Buddy™ App: Available for Android and iOS

For more information about the **Test Buddy™ App**
Click here
healthy-tracks.com

Validated sample types

❯ Capillary paw pad
❯ Capillary ear
❯ Venous

Objective

The objective of this study was to evaluate the performance of the Test Buddy™ Pet-Monitoring Blood Glucose System in canines and felines, including clinical performance validation, system precision, interference testing, and ease of use. The clinical accuracy of the Test Buddy™ System was also compared to that of a leading competitor.

Methods

Research Design

Currently, there are no clinical guidance documents for study designs using blood glucose meters with animal blood samples. The Test Buddy™ System was developed specifically for canines and felines using Trividia Health's expertise that was gained from over 35 years of experience as a developer and manufacturer of blood glucose monitoring systems. This study enrolled canine and feline subjects at 2 testing sites. A minimum of 100 canine subjects and 100 feline subjects provided a minimum of 100 fresh capillary (drawn from the paw pad and/or the ear) and 100 venous blood samples each.

Data Collection

All subjects providing capillary and venous samples fasted for a minimum of 2 hours prior to enrolling in the study; fasting did not exceed 12 hours. Subjects providing only venous samples were not required to fast. First, a trained technician performed a reference assay, using the Yellow Springs Instruments (YSI) 2300 Blood Glucose Analyzer, and a single hematocrit determination on the collected venous sample. The YSI is a biochemical analyzer that measures the glucose concentration in whole blood, plasma, and serum samples and is a recognized reference standard. Next, the technician performed six (6) Test Buddy™ assays, two (2) leading competitor assays, and a final YSI reference assay using the venous sample. A trained technician then performed two (2) Test Buddy™ assays and two (2) leading competitor assays using a capillary blood sample collected from the paw pad followed by two (2) Test Buddy™ assays and two (2) leading competitor assays using a capillary blood sample collected from the ear. Due to subject sample volume limitations, capillary meter results were compared to venous YSI results.

Data Analysis

Capillary and venous blood glucose results obtained from canine and feline subjects using the Test Buddy™ System were compared to results obtained using the YSI 2300 Blood Glucose Analyzer and a leading competitor. Test Buddy™ results versus the YSI reference results and leading competitor results versus the YSI reference results from canine and feline subjects were presented using bias plots and bias tables for capillary, venous, and cumulative (capillary + venous combined) data. The acceptance criterion was the percentage of results from the Test Buddy™ System within the accuracy acceptance criteria listed in EN ISO 15197:2003 (ie, ±15 mg/dL versus the YSI reference value for glucose concentrations <75 mg/dL or within ±20% versus the YSI reference value for glucose concentrations ≥75mg/dL) compared to a leading competitor.

The Parkes Error Grid (a consensus error grid)[10] was used to assess the potential clinical significance of the bias between the Test Buddy™ results versus the YSI reference (and to assess a leading competitor versus the YSI reference). The Parkes Error Grid is divided into 5 zones (A-E), which represent increasing risk levels related to potential clinical outcomes. Glucose results within Zones A and B are associated with no or little effect on clinical outcomes, whereas glucose results within Zones C, D, and E represent altered clinical action with increasing negative effect on clinical outcomes.

The repeatability study for the Test Buddy™ System was conducted per EN ISO 15197:2003 procedures. For interference testing, duplicate samples were prepared with a potential interferent introduced into one and solvent introduced into the other. Both were then evaluated to determine if the addition of the potential interferent affected the accuracy of the glucose measurement. Significant interference with the glucose measurement was considered to have occurred if the mean difference between control sample and test sample biases was >10 mg/dL for glucose test concentrations <100 mg/dL or >10% for glucose test concentrations ≥100 mg/dL.

Ease of use of the Test Buddy™ System was evaluated by veterinary health care professionals and lay users (minimum of 15 each). Users were given the Test Buddy™ meter, test strip vial, control solution, and owner's booklet; they were then asked to read sections of the owner's booklet and perform several glucose tests. Subjects next answered survey questions rating the ease of use of Test Buddy™ System and owner's booklet. A second study evaluated ease of use of the Test Buddy™ App in lay user pet owners familiar with Android and iOS based mobile devices (minimum of 15 each). Subjects were asked to operate the Test Buddy™ App using only the in-app user help guide. After completing several tasks, subjects participated in a 1-on-1 exit interview to provide feedback.

Canine Results

Canine Meter Accuracy

A total of 113 canine subjects provided 91 capillary paw pad, 112 capillary ear, and 113 venous blood samples. The average age of the canine subjects was 3.9 years (range, 0.5-14.0 years), and the average weight was 10.6 kg (23.4 lbs; range, 2.2-38.6 kg [4.9-85.0 lbs]). The average hematocrit was 51% (range, 28%-59%); the average glucose, unaltered, was 102 mg/dL (range, 81-348 mg/dL), and the average glucose, including contrived samples, was 133 mg/dL (range, 34-599 mg/dL).

Table 2. Canine Capillary Accuracy Results Using the Test Buddy™ Versus the YSI Reference Instrument				
Canine capillary paw pad				
	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
Results <75 mg/dL	No samples <75 mg/dL	No samples <75 mg/dL	No samples <75 mg/dL	
	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Results ≥75 mg/dL	30.8% (56/182)	61.5% (112/182)	78.6% (143/182)	86.3% (157/182)
	Within ±15 mg/dL or ±20%			
Both <75 mg/dL and ≥75 mg/dL	86.3% (157/182)			
Canine capillary ear				
	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
Results <75 mg/dL	No samples <75 mg/dL	No samples <75 mg/dL	No samples <75 mg/dL	
	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Results ≥75 mg/dL	27.7% (62/224)	59.8% (134/224)	79.0% (177/224)	87.9% (197/224)
	Within ±15 mg/dL or ±20%			
Both <75 mg/dL and ≥75 mg/dL	87.9% (197/224)			

YSI, Yellow Springs Instruments.

Canine Capillary Testing

A total of 86.3% of canine capillary paw pad results and 87.9% of canine capillary ear sample results using the Test Buddy™ System were within the specified limits of the minimum EN ISO 15197:2003 accuracy criteria (**Table 2**). Using the Parkes Error Grid analysis (consensus error grid analysis) for the Test Buddy™ System versus the YSI reference method for capillary samples, 89.6% and 96.4% of the data points fell within Zone A (no effect on clinical outcomes) for the capillary paw pad and ear samples, respectively.

Canine Venous Testing

A total of 98.8% of venous results using the Test Buddy™ System were within the specified limits of the minimum EN ISO 15197:2003 accuracy criteria (**Table 3**). According to the Parkes Error Grid analysis (consensus error grid analysis) for the Test Buddy™ System versus the YSI reference method for venous samples, 99.4% of the data points fell within Zone A (no effect on clinical outcomes).

Table 3. Accuracy Results Using the Test Buddy™ Versus the YSI Reference Instrument (Canine Venous)				
	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
Results <75 mg/dL	69.0% (29/42)	97.6% (41/42)	100.0% (42/42)	
	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Results ≥75 mg/dL	46.5% (363/780)	76.4% (596/780)	93.7% (731/780)	98.7% (770/780)
	Within ±15 mg/dL or ±20%			
Both <75 mg/dL and ≥75 mg/dL	98.8% (812/822)			

YSI, Yellow Springs Instruments.

Canine Cumulative Results: Test Buddy™ Versus a Leading Competitor

The cumulative canine (capillary paw pad, capillary ear, and venous) results of the Test Buddy™ System and a leading competitor were compared to the YSI reference values (**Tables 4** and **5**). Cumulative canine accuracy results were greater with the Test Buddy™ System than with a leading competitor. The bias (**Figures 3A** and **B**) and consensus error grid analysis (**Figures 3C** and **D**) plots are shown for comparison.

Percent of samples within ±15 mg/dL or ±20% accuracy:

Canine capillary paw pad: **86.3%**

Canine capillary ear: **87.9%**

Percent of samples within ±15 mg/dL or ±20% accuracy:

Canine venous: **98.8%**

Percent of canine results within ±15 mg/dL or ±20% of the reference sample:

Test Buddy™ System:
95.0%

Leading Competitor:
83.1%

Table 4. Cumulative Canine Accuracy Results Using the Test Buddy™ and a Leading Competitor Versus the YSI Reference Instrument

Results <75 mg/dL

	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
Test Buddy™	69.0% (29/42)	97.6% (41/42)	100.0% (42/42)	
Leading Competitor	50.0% (7/14)	100.0% (14/14)	100.0% (14/14)	

Results ≥75 mg/dL

	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Test Buddy™	40.6% (481/1,186)	71.0% (842/1,186)	88.6% (1,051/1,186)	94.8% (1,124/1,186)
Leading Competitor	25.6% (170/665)	53.4% (355/665)	70.2% (467/665)	82.7% (550/665)

Both <75 mg/dL and ≥75 mg/dL

	Within ±15 mg/dL or ±20%
Test Buddy™	95.0% (1,166/1,228)
Leading Competitor	83.1% (564/679)

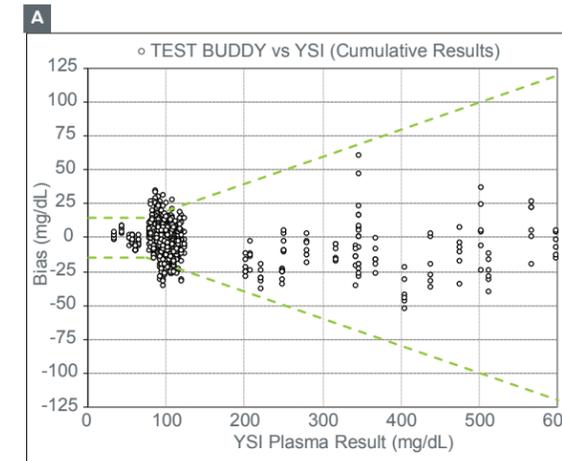YSI, Yellow Springs Instruments.

Table 5. Statistical Analysis of Linear Regression and Consensus Error Grid Analysis for the Test Buddy™ and a Leading Competitor Versus the YSI Reference (Cumulative Canine)

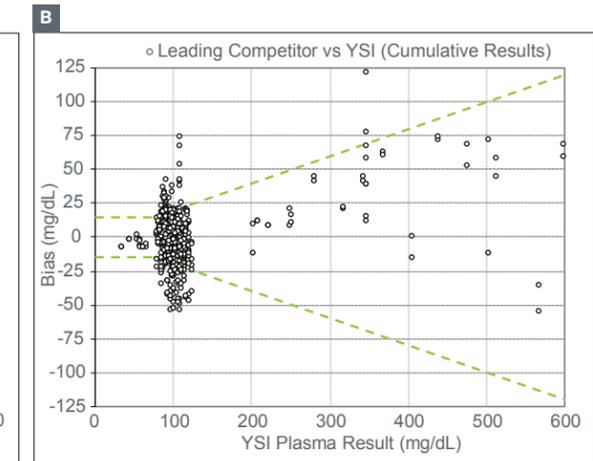|	Test Buddy™	Leading Competitor
Slope (±SE), mg/dL	0.967 (±0.004)	1.109 (±0.010)
Y intercept (±SE), mg/dL	3.146 (±0.558)	−12.421 (±1.351)
Consensus error grid Zone A (no effect on clinical outcomes)	97.4%	87.9%

YSI, Yellow Springs Instruments; SE, standard error.

Figure 3. EN ISO 15197:2003 Accuracy Results for Canine Samples Using Test Buddy™ (A, C) and Leading Competitor (B, D) Versus YSI Reference Instrument

A, B. Bias plot of all Test Buddy™ or Leading Competitor results versus YSI reference instrument results analyzed per the EN ISO 15197:2003 accuracy standard.

C, D. Parkes Error Grid of Test Buddy™ or Leading Competitor results versus YSI reference instrument results.

YSI, Yellow Springs Instruments.
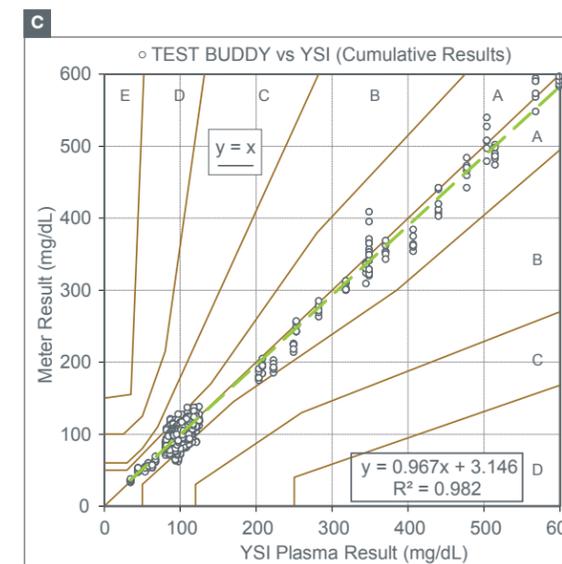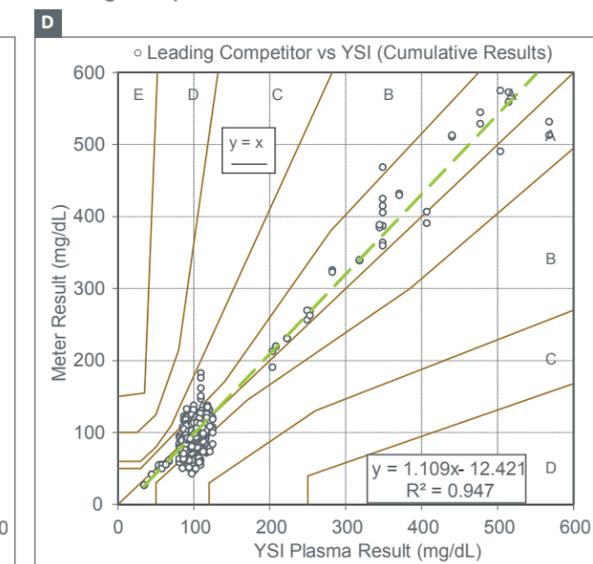
TEST BUDDY™

Feline Results

Feline Meter Accuracy

A total of 114 feline subjects provided 114 capillary paw pad, 114 capillary ear, and 114 venous blood samples. The average age of the feline subjects was 2.5 years (range, 1.0-13.0 years), and the average weight was 5.6 kg (12.4 lbs; range, 2.7-9.1 kg [5.9-20.0 lbs]). The average hematocrit was 36% (range, 28%-50%); the average glucose, unaltered, was 92 mg/dL (range, 73-162 mg/dL), and the average glucose, including contrived samples, was 115 mg/dL (range, 29-536 mg/dL).

Table 6. Feline Capillary Accuracy Results Using the Test Buddy™ Versus the YSI Reference Instrument				
Feline capillary paw pad				
	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
Results <75 mg/dL	50.0% (2/4)	100.0% (4/4)	100.0% (4/4)	
	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Results ≥75 mg/dL	30.8% (69/224)	64.3% (144/224)	83.0% (186/224)	91.5% (205/224)
	Within ±15 mg/dL or ±20%			
Both <75 mg/dL and ≥75 mg/dL	91.7% (209/228)			
Feline capillary ear				
	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
Results <75 mg/dL	0.0% (0/4)	25.0% (1/4)	100.0% (4/4)	
	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Results ≥75 mg/dL	27.7% (62/224)	51.8% (116/224)	77.2% (173/224)	93.3% (209/224)
	Within ±15 mg/dL or ±20%			
Both <75 mg/dL and ≥75 mg/dL	93.4% (213/228)			

YSI, Yellow Springs Instruments.

Percent of samples within ±15 mg/dL or ±20% accuracy:

Feline capillary paw pad:
91.7%

Feline capillary ear:
93.4%

Feline Capillary Testing

A total of 91.7% of feline capillary paw pad results and 93.4% of feline capillary ear sample results using the Test Buddy™ System were within the specified limits of the minimum EN ISO 15197:2003 accuracy criteria (**Table 6**). According to the Parkes Error Grid analysis (consensus error grid analysis) for the Test Buddy™ System versus the YSI reference method for capillary samples, 93.4% and 98.2% of the data points were within Zone A (no effect on clinical outcomes) for the capillary paw pad and ear samples, respectively.

Feline Venous Testing

A total of 97.9% of venous results using the Test Buddy™ System were within the specified limits of the minimum EN ISO 15197:2003 accuracy criteria (**Table 7**). According to the Parkes Error Grid analysis (consensus error grid analysis) for the Test Buddy™ System versus the YSI reference method for venous samples, 100.0% of the data points were within Zone A (no effect on clinical outcomes).

Table 7. Accuracy Results Using the Test Buddy™ Versus the YSI Reference Instrument (Feline Venous)				
	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
Results <75 mg/dL	48.1% (26/54)	83.3% (45/54)	98.1% (53/54)	
	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Results ≥75 mg/dL	28.9% (224/774)	59.4% (460/774)	84.8% (656/774)	97.9% (758/774)
	Within ±15 mg/dL or ±20%			
Both <75 mg/dL and ≥75 mg/dL	97.9% (811/828)			

YSI, Yellow Springs Instruments.

Feline Cumulative Results: Test Buddy™ Versus a Leading Competitor

The cumulative feline (capillary paw pad, capillary ear, and venous) results of the Test Buddy™ System and a leading competitor were compared to the YSI reference values (**Tables 8** and **9**). Cumulative feline accuracy results were greater with the Test Buddy™ System than with a leading competitor. The bias (**Figures 4A** and **B**) and consensus error grid analysis (**Figures 4C** and **D**) plots are shown for comparison.

Percent of samples within ±15 mg/dL or ±20% accuracy:

Feline venous:
97.9%

Percent of feline results within ±15 mg/dL or ±20% of the reference sample:

Test Buddy™ System:
96.0%

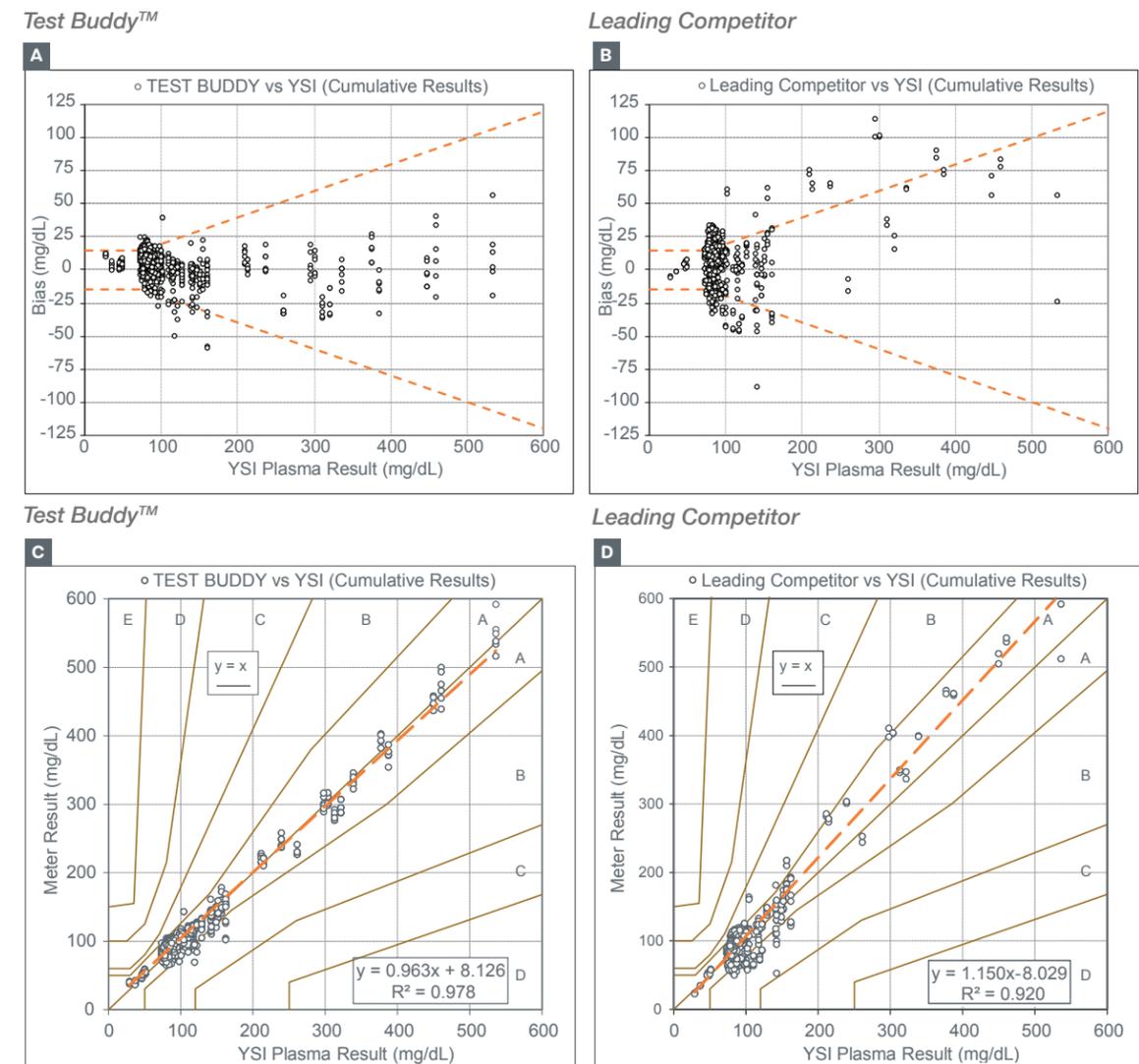Leading Competitor:
73.6%

Table 8. Cumulative Feline Accuracy Results Using the Test Buddy™ and a Leading Competitor Versus the YSI Reference Instrument

Results <75 mg/dL	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
Test Buddy™	45.2% (28/62)	80.6% (50/62)	98.4% (61/62)	
Leading Competitor	42.3% (11/26)	76.9% (20/26)	96.2% (25/26)	
Results ≥75 mg/dL	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Test Buddy™	29.1% (355/1,222)	58.9% (720/1,222)	83.1% (1,015/1,222)	95.9% (1,172/1,222)
Leading Competitor	17.6% (124/706)	32.0% (226/706)	50.4% (356/706)	72.8% (514/706)
Both <75 mg/dL and ≥75 mg/dL	Within ±15 mg/dL or ±20%			
Test Buddy™	96.0% (1,233/1,284)			
Leading Competitor	73.6% (539/732)			

YSI, Yellow Springs Instruments.

Table 9. Statistical Analysis of Linear Regression and Consensus Error Grid Analysis for the Test Buddy™ and a Leading Competitor Versus the YSI Reference (Cumulative Feline)

	Test Buddy™	Leading Competitor
Slope (±SE), mg/dL	0.963 (±0.004)	1.150 (±0.013)
Y intercept (±SE), mg/dL	8.126 (±0.513)	−8.029 (±1.426)
Consensus error grid Zone A (no effect on clinical outcomes)	98.5%	90.6%

YSI, Yellow Springs Instruments; SE, standard error.

Figure 4. EN ISO 15197:2003 Accuracy Results for Feline Samples Using Test Buddy™ (A, C) and Leading Competitor (B, D) Versus YSI Reference Instrument

A, B. Bias plot of all Test Buddy™ or Leading Competitor results versus YSI reference instrument results analyzed per the EN ISO 15197:2003 accuracy standard.

C, D. Parkes Error Grid of Test Buddy™ or Leading Competitor results versus YSI reference instrument results.

YSI, Yellow Springs Instruments.

Precision Verification

According to the repeatability precision verification of the Test Buddy™ Pet-Monitoring Blood Glucose System, all meter results were within the established acceptance criteria for canine (**Table 10**) and feline use (**Table 11**).

Precision Verification: Canine Test Mode

Table 10. Canine Within-vial Precision Summary of Mean, SD, and %CV of Meters (n = 10)						
Test Strip Lot		Level 1	Level 2	Level 3	Level 4	Level 5
1	Mean (mg/dL)	43	76	133	195	309
	SD (mg/dL)	1.3	1.9	3.6	4.8	8.1
	%CV	3.0%	2.4%	2.7%	2.5%	2.6%
2	Mean (mg/dL)	42	75	133	197	322
	SD (mg/dL)	1.1	2.0	3.4	4.3	6.6
	%CV	2.7%	2.7%	2.5%	2.2%	2.1%
3	Mean (mg/dL)	43	77	137	202	325
	SD (mg/dL)	1.1	2.0	3.8	6.4	8.3
	%CV	2.6%	2.6%	2.8%	3.2%	2.6%
Average	Mean (mg/dL)	42	76	134	198	319
	SD (mg/dL)	1.2	2.0	3.6	5.2	7.7
	%CV	2.8%	2.6%	2.7%	2.6%	2.4%

SD, standard deviation; CV, coefficient of variation.

Precision Verification: Feline Test Mode

Table 11. Feline Within-vial Precision Summary of Mean, SD, and %CV of Meters (n = 10)						
Test Strip Lot		Level 1	Level 2	Level 3	Level 4	Level 5
1	Mean (mg/dL)	40	65	113	162	265
	SD (mg/dL)	1.5	1.8	3.0	3.9	6.1
	%CV	3.7%	2.8%	2.7%	2.4%	2.3%
2	Mean (mg/dL)	39	64	113	165	276
	SD (mg/dL)	1.4	1.8	3.0	4.6	7.4
	%CV	3.7%	2.9%	2.7%	2.8%	2.7%
3	Mean (mg/dL)	40	66	118	172	283
	SD (mg/dL)	1.6	2.2	3.2	4.4	7.4
	%CV	3.9%	3.3%	2.7%	2.6%	2.6%
Average	Mean (mg/dL)	40	65	115	166	275
	SD (mg/dL)	1.5	1.9	3.1	4.3	7.0
	%CV	3.8%	3.0%	2.7%	2.6%	2.5%

SD, standard deviation; CV, coefficient of variation.

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Interference Testing

Table 12. Actual Test Concentrations and Differences in Bias Results for Potential Interference Substances at 75 mg/dL Glucose Level					
Potential Interferent	Test Concentration (mg/dL)	Sample 1	Sample 2	Sample 3	Mean Difference in Bias (mg/dL)
Analgesic, Sedative, Anti-inflammatory, or Corticosteroid					
Acetaminophen	232.6	5	7	7	6.3
Dexmedetomidine	0.22	0	2	4	2.0
Prednisolone	43.7	4	1	0	1.7
Salicylic Acid (Salicylate)	800	4	1	3	2.7
Xylazine	12	1	3	2	2.0
Flea & Tick Prevention, Antibiotic, Antiparasitic, or Insecticide					
Fipronil	59.4	7	9	8	8.0
Metronidazole	272.7	3	4	3	3.3
Milbemycin Oxime	232.56	10	1	3	4.7
Selamectin	83.7	2	1	0	1.0
S-Methoprene	71.5	1	0	0	0.3
Spinosad	250	6	8	6	6.7
Tetracycline	120	7	2	3	4.0
Antidiabetic Agent					
Glipizide	60.6	0	0	2	0.7
Metformin	10.9	1	2	4	2.3
Endogenous*					
Total Bilirubin	1.5	2	1	1	1.3
Cholesterol	578	1	0	0	0.3
Creatinine	7.5	3	3	4	3.3
Hemoglobin	3,000	6	9	7	7.3
Reduced Glutathione	92	7	9	6	7.3

Table 12 (cont'd).					
Potential Interferent	Test Concentration (mg/dL)	Sample 1	Sample 2	Sample 3	Mean Difference in Bias (mg/dL)
Sodium	136.8 mEq/L (mmol/L)	2	1	1	1.3
Triglyceride	720	2	2	2	2.0
Uric acid	2.1	1	3	0	1.3
Supplement					
Ascorbic Acid	4	6	9	8	7.7
Diuretic or Laxative					
Mannitol	250	6	5	8	6.3
Sorbitol	10,000	8	6	7	7.0
Anticoagulant					
EDTA	360	7	7	7	7.0
Lithium Heparin	75 U/mL	2	3	4	3.0
Sodium Heparin	66 U/mL	1	2	1	1.3
Adrenergic/Dopaminergic Inotropic Agent					
Dopamine	400	5	2	0	2.3
Hormone					
Megestrol Acetate	121.2	2	2	3	2.3
Progesterone	21.8	2	1	1	1.3
Poison Antidote					
PAM	220.9	3	4	0	2.3
Anti-convulsant					
Potassium Bromide	500	2	4	4	3.3

EDTA, ethylenediaminetetraacetic acid; PAM, pralidoxime iodide or chloride.

*Test concentrations represent spiked levels that are in addition to endogenous levels already present in the specimens.

Interference Testing

A number of the medications used in veterinary medicine for canines and felines were evaluated through extensive interference testing to demonstrate that the Test Buddy™ System can be used to provide accurate results in animals being treated for various disease states or in cases of accidental ingestion. Results of this interference testing are shown in **Table 12**. Concentrations in which significant interference did not occur were identified for the system; these concentrations met pre-established acceptance criteria.

EDTA was evaluated as an anticoagulant in a "short draw" of a blood sample based on a 2 mL vacutainer tube. Significant interference occurred with draw volumes lower than 1 mL, suggesting that blood samples from a 2 mL vacutainer tube with EDTA that contains <1 mL of blood may interfere with glucose results. Draw volumes above this value were acceptable.

Blood samples containing >16% hemolysis caused interference with glucose test results. If hemolysis is detected, a fresh sample should be used for blood glucose testing.

Test Buddy Test Strips are for use with fresh, capillary or fresh, venous whole blood samples taken from a dog or cat. A short draw into an EDTA collection tube that is less than half of the designated fill volume may cause falsely low results. Ingestion of supplements containing Vitamin C may cause falsely high glucose results (blood concentrations of >4 mg/dL Vitamin C). Hemolysis (broken red blood cells) may cause falsely low glucose results. Obtain a new venous blood sample prior to testing if there are indications that the blood may be hemolyzed.

Ease of Use

In the human factors usability and ease of use studies of veterinary technicians and lay users, there were no observed use errors with the Test Buddy™ System or App that resulted in unacceptable risk or potential harm to the user or pet. The majority of users were able to successfully accomplish the various tasks using the Test Buddy™ System or App, and most users found the tasks were very easy or easy to complete.

Conclusions

The percentage of cumulative (capillary paw pad, capillary ear, and venous) results within the accuracy requirements of the EN ISO 15197:2003 standard was 95.0% for the canine meter accuracy testing and 96.0% for the feline meter accuracy testing. The percentage of cumulative results within Zone A of the Parkes Error Grid analysis was 97.4% for canine samples and 98.5% for feline samples, indicating no effect on clinical outcomes.

Compared with a leading competitor, cumulative accuracy results were better with the Test Buddy™ System for both canine and feline samples. More specifically, the percentage of cumulative results within the accuracy requirements of the EN ISO 15197:2003 standard was 95.0% with the Test Buddy™ versus 83.1% with a leading competitor for canine samples and 96.0% versus 73.6%, respectively, for feline samples. Moreover, in both canines and felines, the percentage of results within the accuracy requirements of the EN ISO 15197:2003 standard was greater with the Test Buddy™ than with a leading competitor for all the individual anatomical sample sites tested: capillary paw pad, capillary ear, and venous.

Additional analyses confirmed consistent Test Buddy™ production quality, with all acceptance criteria met for each test strip lot. Results of interference testing indicated that other than Vitamin C and sampling factors such as small draw volume and hemolysis, most of the wide variety of substances tested did not interfere with Test Buddy™ System performance. Usability and ease of use were demonstrated for both the Test Buddy™ Pet-Monitoring Blood Glucose System and the Test Buddy™ App.

The Test Buddy™ Pet-Monitoring Blood Glucose System from Trividia Health demonstrates proven precision, accuracy, and ease of use when measuring blood glucose in canines and felines. The accuracy and precision generated by an easy-to-use blood glucose monitor that is designed for species-specific use contribute to overall product performance and improved management of diabetes in pets.

Healthy Tracks™ for Pets

For more information about the **Healthy Tracks for Pets™ portfolio of products**

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