TEST BUDDY™ Pet-Monitoring Blood Glucose Test Strips - Instructions for Use

To obtain Instructions for Use in Spanish, go to www.testbuddymeter.com.

Important! Read all instructions for use (meter, test strips, control solution, lancing device) and practice testing before using the Test Buddy™ System to measure blood glucose. Seek the guidance of a veterinarian before monitoring blood glucose.

Intended Use

Test Buddy™ Pet-Monitoring Blood Glucose Test Strips are for use only with the Test Buddy Pet-Monitoring Blood Glucose Meter to quantitatively measure blood glucose in fresh, whole blood samples taken from dogs or cats. **NOT FOR HUMAN USE.**

The Test Buddy™ System is intended for home and professional/veterinary clinic use for monitoring blood glucose samples taken from dogs (canines) or cats (felines).

Test Buddy Test Strips are for *in vitro* (outside the body) diagnostic use only.

Test Buddy Test Strips are intended for testing with:

- fresh, capillary whole blood samples from the ear or paw pad, and
- fresh, venous whole blood collected into an EDTA blood collection tube. A short draw into an EDTA collection tube that is less than half of the designated fill volume may cause falsely low results.

Test strips for single use only – do not reuse.

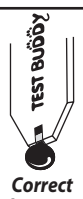
Test Principle

The Test Buddy Test Strip is a plastic strip containing chemicals and electrodes. The Test Buddy Test Strips and Meter measure blood glucose using amperometric technology employing a glucose dehydrogenase-FAD reaction. When a blood or control solution sample is applied to the test strip, glucose in the sample reacts with the test strip chemicals to produce an electrical current. The meter measures the current, detects and corrects for hematocrit and temperature, and calculates the glucose result. The result is displayed as a plasma value.

Chemical Composition

Glucose dehydrogenase-FAD *(Aspergillus species)*, mediators, buffer, and stabilizers.

① **Contact End** - End inserted into meter.
② **Sample Tip** - End where sample is drawn into test strip.



Correct Placement

Incorrect Placement

WARNING!

After opening the test strip carton, check the test strip vial for missing, damaged, or broken parts. Check that the cap is securely closed. If the vial is damaged or the cap is not closed, do not use the test strips for testing as the test strips may give inaccurate results. Contact Customer Care for replacement.

Care and Storage

- Store in a dry place at room temperature below 86°F. **DO NOT REFRIGERATE OR FREEZE.**
- Store test strips in the original vial only. **Do not** transfer test strips to a new vial or store outside the vial. **Do not** store in bathroom or kitchen. Keep away from direct sunlight, extreme heat, cold, or high humidity.
- **Write the date on the vial label when you open a new test strip vial. Discard test strips either:**

  - 4 months after the written date has passed (this is the open vial expiration date), OR

  - after the expiration date printed on the label (EXP) has passed, whichever comes first.
- Close vial immediately after removing a test strip. Use test strip quickly after removing from vial. If the test strip has been out of the vial for too long before testing, an error message appears after it is inserted into the meter.
- **Do not** bend, cut, or alter test strips in any way. Discard any damaged test strips or vials.

Important Information

- Use Test Buddy Test Strips only with the Test Buddy Meter and Test Buddy Control Solution. Using other meters or control solutions may give inaccurate results.
- Test Buddy Test Strips contain small parts that may be dangerous if swallowed. Keep out of reach of children and pets.
- **Do not** use for the screening or diagnosis of diabetes.
- Contact with blood presents an infection risk. Wash your hands thoroughly with soap and warm water before and after handling the meter, lancing device, lancets, or test strips. Discard used test strips and lancets into an appropriate waste container.
- **Do not** smear or scrape the sample drop with the test strip.
- **Do not** apply more sample to the test strip after testing begins.
- **Do not** insert the test strip sample tip with blood or control solution into the meter test port as this may damage the meter.
- **NEVER** reuse test strips. **NEVER** wipe test strips with water, alcohol or any cleaner. **Do not** attempt to remove blood or control solution from test strips or clean test strips and re-use. Reuse of test strips will cause inaccurate results.
- If you have any liquids on your hands, especially blood, make sure you wash and thoroughly dry your hands before opening the test strip vial.
- If blood or liquid gets into the test strip vial, discard vial and use a new vial for testing. Using test strips that may have become contaminated may result in incorrect results or error messages.
- All parts of the system could carry blood-borne pathogens after use, even after cleaning and disinfecting. For instructions on cleaning and disinfecting the meter and lancing device, see the *Meter Cleaning and Disinfecting* and *Lancing Device Cleaning and Disinfecting* sections in the *Test Buddy Owner's Booklet*.

References

1. Bruyette, D. "Diabetes Mellitus in Dogs and Cats." Merck Veterinary Manual, Jul. 2019. www.merckvetmanual.com/endocrine-system/the-pancreas/diabetes-mellitus-in-dogs-and-cats. Accessed 6/30/2020.
2. Data on file.
3. Parkes, J, Pardo, S, Slatin, S, & Ginsberg, B 2000, 'A New Consensus Error Grid to Evaluate the Clinical Significance of Inaccuracies in the Measurement of Blood Glucose', Diabetes Care, vol. 23, no.8, p1145.

TEST BUDDY™

X3HTK03R1

TEST BUDDY™

Quality Control Testing

The Test Buddy System has two kinds of quality control tests to ensure that the system is working properly and that your testing technique is good.

Automatic Self-Test

The meter performs an automatic self-test each time a test strip is inserted correctly into the test port. The meter is working properly if:

- the full display appears, then
- the time, cat or dog icon, and blinking drop appear.

See the *Automatic Self-Test* section in the *Test Buddy Owner's Booklet* for more information.

Control Solution Test

Test Buddy Control Solution is used to check testing technique and the performance of the Test Buddy Meter and Test Strips. Three levels (1, 2, 3) of control solution are available. The acceptable range for each control solution level is printed on the test strip vial label.

The system is working properly if the control solution test result is within the range printed on the test strip vial label for the control solution level you are using. See the *Control Solution Test* section in the *Test Buddy Owner's Booklet* for more information.

Important! Perform control tests with more than one level of control solution to ensure that your system is working properly and your testing technique is good.

For information on how to obtain different levels of control solution **call Customer Care at 1-800-803-6025, Mon.–Fri., 8AM–8PM EST.**

Blood Glucose Testing

Important! Read the *Test Buddy Owner's Booklet* for detailed instructions on how to perform a blood glucose test.

1. Check the test strip and control solution expiration dates. **Do not** use expired test strips or control solution.
2. Wash and dry hands.
3. Wash and dry the test site (e.g. ear or paw pad). Dry hands thoroughly.
4. Take one test strip from the vial. Recap the vial right away.
5. Insert the test strip contact end into the meter test port. The meter turns on and performs an automatic self-test. **Check that the correct animal type (dog or cat) is displayed.**
6. Lance the test site and obtain a blood drop.
   Note to veterinary professionals:
   Fresh, venous whole blood collected into an EDTA blood collection tube may be used for testing. Mix tube well before sampling. A short draw into an EDTA collection tube that is less than half of the designated fill volume may cause falsely low results.
7. **Touch the test strip sample tip to the top of the blood drop. Do not put the blood drop on top of the test strip.**
8. Hold the test strip to the blood drop until the meter beeps and dashes move across the display. Remove the test strip sample tip from the blood drop. If the meter does not begin testing soon after touching the sample tip to the blood drop, discard the test strip. Retest with a new test strip and new blood drop. If the problem continues or an error message appears, see the *Troubleshooting* section in the *Test Buddy Owner's Booklet*.
9. The result displays when the test is completed. The result is stored in meter memory with the date and time. If desired, mark the result with an Event Tag.
10. Hold the meter with the test strip pointing down. Press the strip release button to discard the test strip into a suitable waste container. The meter turns off.

Caution! *Used lancets and test strips are considered biohazardous. Discard carefully into a suitable waste container.*

Understanding Blood Glucose Test Results

The normal fasting glucose range for dogs and cats without diabetes is: 75–120 mg/dL.[1] A veterinarian will determine the blood glucose target range for your dog or cat and how often to test.

Lo and Hi Results

The Test Buddy meter reads blood glucose levels from 20–600 mg/dL. Low or high blood glucose results may mean there is a serious medical condition.

- If the result is less than 20 mg/dL, Lo appears in the meter display.
- If the result is greater than 600 mg/dL, Hi appears in the meter display.

Always repeat the test to confirm Lo or Hi results. If the meter still displays Lo or Hi, contact your veterinarian immediately.

Troubleshooting

If the blood glucose result is unusually low or high, or unexpected, perform a Control Solution Test (see *Quality Control Testing - Control Solution Test*).

If the control test result is within the range for the control solution level you are using:

- Read the *Blood Glucose Testing* section and repeat the blood glucose test with a new Test Buddy test strip.

If the control test result is not within the range:

- Check the test strip and control solution expiration dates. **Do not** use expired test strips or control solution. If test strips or control solution has expired, discard them. Test with new test strips and/or control solution.
- Check your testing technique. Read the *Quality Control Testing* section and repeat the control solution test.
- If an error message appears, follow the instructions in the *Error Messages* section in the *Test Buddy Owner's Booklet*.

Contact your veterinarian if the blood glucose test result is not consistent with any visible symptoms.

Limitations[2]

- Test Buddy Test Strips are for use with fresh, capillary or fresh, venous whole blood samples taken from a dog or cat. **NOT FOR HUMAN USE.**
- Use Test Buddy Test Strips only within the system operating conditions: 50°F–104°F, relative humidity 10%–90% (non-condensing).
- Testing at altitudes greater than 10,150 ft may cause inaccurate results.
- Hematocrit levels below 20% or above 60% may cause inaccurate results.
- 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.

Call Customer Care for assistance at 1-800-803-6025, Mon.–Fri., 8AM–8PM EST.

Manufactured by:
TRIVIDIA HEALTH™
Fort Lauderdale, FL 33309 U.S.A.

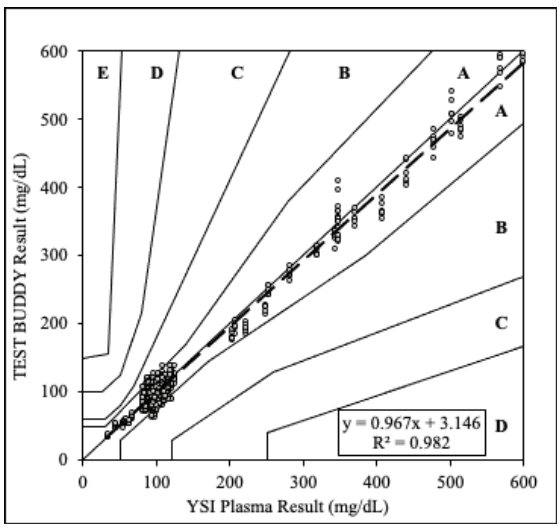
X3HTK03 Rev. 1

Performance Characteristics

Accuracy

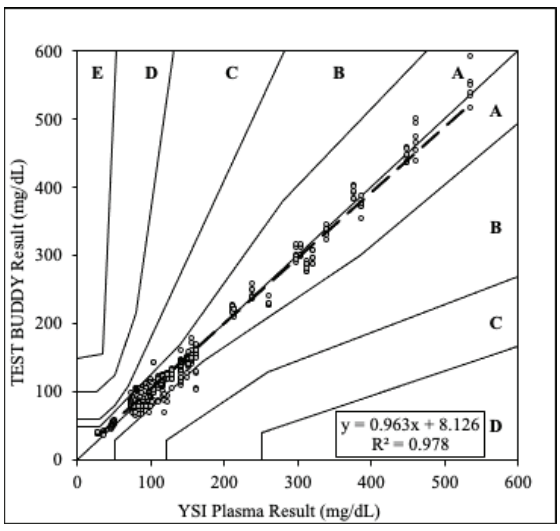
The Test Buddy Pet-Monitoring Blood Glucose System was tested at a research center and veterinary animal hospital. The data was compared to parallel results obtained on a Yellow Springs Instrument (YSI). The figures and tables below show that the Test Buddy Pet-Monitoring Blood Glucose System achieves accurate results.

Consensus Error Grid Analysis for Test Buddy
Canine test results (Paw Pad, Ear, and Venous) vs. YSI reference (mg/dL)
(3 Test Strip Lots Combined)



Consensus Error Zone Count (Canine)		
ZONE	**# Points**	**%**
A	1196	97.4%
B	32	2.6%
C	0	0.0%
D	0	0.0%
E	0	0.0%

Consensus Error Grid Analysis for Test Buddy
Feline test results (Paw Pad, Ear, and Venous) vs. YSI reference (mg/dL)
(3 Test Strip Lots Combined)



Consensus Error Zone Count (Feline)		
ZONE	**# Points**	**%**
A	1265	98.5%
B	19	1.5%
C	0	0.0%
D	0	0.0%
E	0	0.0%

The Consensus Error grid is divided into zones signifying the degree of risk posed by the incorrect measurement: Zone A represents no effect on clinical action; Zone B represents altered clinical action—little or no effect on clinical outcome; Zone C represents altered clinical action—likely to affect clinical outcome; Zone D represents altered clinical action—could have significant medical risk; and Zone E represents altered clinical action—could have dangerous consequences.[3]

Interferents

Interference effects were assessed by spiking potential interferents or endogenous substances into naturally occurring canine and feline specimens. The following substances will not significantly interfere with the Test Buddy glucose measurements at or below the stated test concentrations.

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

Substance Type	Substance	Brand Name	Test Concentration
Analgesic, Sedative, Anti-inflammatory, or Corticosteroid	Acetaminophen	Tylenol®, APAP, Paracetamol	232.6 mg/dL
	Dexmedetomidine	Dexdomitor®, Sileo®	0.22 mg/dL
	Prednisolone	---	43.7 mg/dL
	Salicylic Acid	Solva-ker™ gel	800 mg/dL
	Xylazine	Rompun®	12 mg/dL
Flea & Tick Prevention, Antibiotic, Antiparasitic, or Insecticide	Fipronil	Frontline®	59.4 mg/dL
	Metronidazole	Flagyl®	272.7 mg/dL
	Milbemycin Oxime	Interceptor™	232.6 mg/dL
	Selamectin	Revolution®, Paradyne®	83.7 mg/dL
	S-Methoprene	---	71.5 mg/dL
	Spinosad	Comfortis®, Trifexis®	250 mg/dL
	Tetracycline	---	120 mg/dL
Antidiabetic Agent	Glipizide	Glucotrol®	60.6 mg/dL
	Metformin	Glucophage®	10.9 mg/dL
Endogenous*	Total Bilirubin	---	1.5 mg/dL
	Cholesterol	---	578 mg/dL
	Creatinine	---	7.5 mg/dL
	Hemoglobin	---	3,000 mg/dL
	Reduced Glutathione	---	92 mg/dL
	Sodium	---	136.8 mEq/L (mmol/L)
	Triglyceride	---	720 mg/dL
	Uric acid	---	2.1 mg/dL
Supplement	Ascorbic Acid	Vitamin C	4 mg/dL
Diuretic or Laxative	Mannitol	Osmitrol®	250 mg/dL
	Sorbitol	---	10,000 mg/dL
Anticoagulant	EDTA	---	360 mg/dL
	Lithium Heparin	---	75 U/mL
	Sodium Heparin	---	66 U/mL
Adrenergic/ Dopaminergic Inotropic Agent	Dopamine	---	400 mg/dL
Hormone	Megestrol Acetate	Ovaban®, Megace®	121.2 mg/dL
	Progesterone	---	21.8 mg/dL
Poison Antidote	Pralidoxime Chloride	PAM, Protopam® Chloride	220.9 mg/dL
Anti-Convulsant	Potassium Bromide	---	500 mg/dL

Linearity

Linearity is the ability of the system (within a given range) to provide results that are directly proportional to the concentration of glucose in the blood sample. Linearity testing was performed at a research center and veterinary animal hospital. The table below shows that the Test Buddy Pet-Monitoring Blood Glucose System achieves linear results.

Canine and Feline statistical analysis of linear regression for Test Buddy test results (Paw Pad, Ear, and Venous) vs. YSI reference (mg/dL)

Statistical Analysis	Canine	Feline
Intercept	3.146	8.126
Slope	0.967	0.963
Data Points (n=)	1228	1284
Minimum Glucose Value	34 mg/dL	29 mg/dL
Maximum Glucose Value	599 mg/dL	536 mg/dL

Precision

Precision describes the variation between results. Precision testing was performed in a laboratory. The tables below show that the Test Buddy Pet-Monitoring Blood Glucose System achieves precise results.

Within-vial precision summary of mean, standard deviation, and %CV of meters set to Canine test mode

Canine Meter Mode: Within-Vial Precision (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%

Within-vial precision summary of mean, standard deviation, and %CV of meters set to Feline test mode

Feline Meter Mode: Within-Vial Precision (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%