*Gen*Ultimate!® Test Strips Instructions

IMPORTANT: Please read this entire pamphlet before using GenUltimate® Test Strips.

INTENDED USE

Genstrip® (and Genstrip50® and GenUltimate!®) Test Strips with calibration codes 4, 10, and 13 are for use with OneTouch® Ultra®, Ultra®2, and UltraMini® meters. They are used to quantitatively measure glucose in fresh capillary whole blood samples taken from the finger, forearm or palm. Testing is done outside the body (in vitro diagnostic use). They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control. The system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

STORAGE AND HANDLING

- Do not use your GenUltimate® Test Strips if the vial has been damaged or opened. This could cause incorrect test results or incorrect meter messages.
- Store test strips only in the original vial. This will avoid contamination or damage. Do not transfer test strips out of the original vial.
- Store test strips in a cool, dry place between 40°F - 86°F (4°C - 30°C). Do not refrigerate. Do not freeze. Do not expose to direct sunlight or heat. Extreme temperatures or humidity may cause inaccurate readings.
- Close vial tightly immediately after you remove a test strip.
- Use each test strip as soon as you take it out of the vial.
- The "Discard date" is 90 days after you first open a vial. Write this number on the vial. Discard any unused test strips after that date.
- Each box of test strips has an expiration date printed on it. Do not use test strips beyond the expiration date.
- Discard test strips on the expiration date or "Discard date", whichever comes first.
- Never get food, dirt or liquids on the test strip. Use only clean hands to touch the test strip. The test strip may be touched anywhere on its surface with clean, dry hands.
- Never bend, cut, damage, or change the test strips in any way.
- Use each test strip only once. Never reuse a test strip that has blood or control solution on it.
- After doing a test do not return the test strip to the vial.
- Use test strips only with OneTouch® Ultra® Control Solution, or whole blood.
- Your meter and test strips should be about the same temperature when you test.

WARNINGS

- Test strips are a choking hazard. Keep away from children. Do not swallow test strips.
- The vial contains a drying agent. This agent can cause injury if inhaled or swallowed or can irritate the skin or eyes.

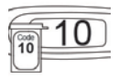

Diagram A

PRECAUTIONS

- Code your Meter to match the code printed on your test strip vial.
  [Caution: You MUST match the code on the Meter to the code on the test strip vial to get accurate readings. Make sure code numbers match each time you test. (See Diagram A.)]
- Your Meter uses a unit of measure to report test results (mg/dl or mmol/L). Make sure your Meter is set correctly. Refer to your Meter instructions for the correct unit of measure. If the unit of measure is not correct, contact the Meter Manufacturer for help.
- If you have symptoms that are not consistent with your test results and you have ruled out common errors described in instructions for your test strips and Meter, call your health care professional immediately.
- Do not change your diabetes treatment or ignore your symptoms without calling your healthcare professional.
- Review your 14-day and 30-day test averages periodically. If they do not seem correct, call your healthcare professional.

MEASURING BLOOD GLUCOSE

NOTE: In addition to GenUltimate® Test Strips, you will need your Meter, meter instructions, lancing device, and lancet.

Collect a blood sample

NOTE: Read Meter instructions for details about using a lancing device.

Step #1: Select a blood sample site. This may be your finger, forearm, or palm. Wash your hands and the site with warm, soapy water. Dry thoroughly.

Step #2: Use a lancing device and a sterile lancet to get a blood drop. The blood drop must be at least 1.0 microliter (1.0 µl). DO NOT squeeze the site too much.

CAUTION: Palm and forearm results may differ from fingertip results when glucose levels are changing rapidly. This can occur after a meal, after taking insulin, or during or after exercise.

Choose the right sample site

If you test:	Use a blood sample:
Regularly before meals	Fingertip, palm or forearm
Before or more than two hours after: A rapid-acting insulin injection Exercise A meal	Fingertip, palm or forearm
When your blood glucose is changing rapidly, such as: Within two hours after a meal Within two hours after a rapid-acting insulin Injection or insulin pump bolus, or During or within two hours after exercise	Fingertip
When you are concerned about possible hypoglycemia	Fingertip

In addition, use fingertip blood and do not rely on palm or forearm test results, if:

- You are not aware of symptoms when you become hypoglycemic
- The site results do not agree with the way you feel
- During illness
- During times of stress
- AST measurements should never be used to calibrate continuous glucose monitors (CGMs)
- AST measurements should never be used in insulin dosing calculations

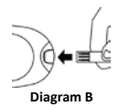

Diagram B

Consult your healthcare professional before you test palm or forearm sites.

Testing your blood glucose

Step #1: Remove test strip from vial. Immediately close the vial tightly. Insert test strip into Meter. Insert the contact bar end first with the strip facing up (See Diagram B.) Gently push test strip into Meter until it stops. This will turn on the Meter. Make sure the Meter and GenUltimate® Test Strip codes match.

Caution: OneTouch® Ultra®, Ultra®2 and UltraMini® meters require coding. Read Meter instructions for details on coding your Meter.

Step #2: The meter will show when it is ready for a blood sample. Some meters show the words "Apply Sample". Other meters use a flashing symbol that means "Apply Sample". Refer to your Meter instructions.

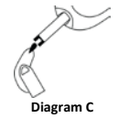

Diagram C

Step #3. Hold the blood drop to the narrow channel at the tip of the test strip (See Diagram C.)

- Do not apply blood to the top surface or underside of the strip.
- Do not press the strip against the test site. Touch only the blood drop with the tip of the test strip.
- Do not smear blood.

Look at the test strip confirmation window. It needs to be completely filled before the Meter counts down. Do not add more blood to the test strip if window is not full- discard test strip. Use a new test strip and repeat the test. If the window is not full, you may get an inaccurate reading or a Meter error message. If you have a problem filling the test strip, contact GenUltimate® Customer Service for help.

Step #4: Your meter will count down from 5 to 1. This will take about 5 seconds. It will then display your test results.

Test Results

Your Meter can display results from 20 to 600 mg/dl (1.1-33.3 mmol/L). Results below 20 mg/dl (1.1mmol/L) will trigger a Meter error message. This could indicate severe hypoglycemia (very low blood glucose). Results above 600 mg/dl (33.3 mmol/L) will trigger a Meter error message. This may indicate severe hyperglycemia (very high blood glucose). If your readings are very low or high, retest. If results are still low or high, call your healthcare professional or seek medical help immediately.

If your results are not what you expect (below 70mg/dl or 3.9 mmol/L which indicates very low blood sugar; or above 180mg/dl or 10.0 mmol/L which indicates very high blood sugar) you should contact your healthcare professional immediately. Check your meter results with control solution. If your symptoms are not consistent with your test results contact your healthcare professional immediately.

EXPECTED VALUES

People without diabetes have these expected blood glucose levels[1]:

Before meals	70 – 130 mg/dl (3.9 - 7.2 mmol/L)
2 hour after any meal	Less than 180 mg/dl (10.0mmol/L)

Diagram D

CHECKING THE SYSTEM

NOTE: Control solution testing must be done only between 68°F (20°C) and 77°F (25°C).

Apply control solution as shown in Diagram D. Squeeze the control solution bottle until a large drop appears. Touch the drop to the tip of the test strip.

Run a Control Solution Test:

- At least weekly.
- When you open a new vial of test strips.
- If you think the Meter or test strips are not working correctly.
- If you have repeated results that do not seem correct.
- If you drop or damage the Meter.
- If you have exposed the test strips to extreme heat, cold, or high humidity.

Use only OneTouch® Ultra® Control Solution. Refer to Meter instructions for full details.
If control solution results fall outside of the range printed on the GenUltimate® Test Strip vial, repeat the test and refer to Meter instructions.

CAUTION: If 2 to 3 control solution results fall out of range, your test strips or Meter may not be working correctly. Do not test your blood with the test strips and Meter until you get control solution results that are in range. If you continue to have problems, contact GenUltimate® Customer Service or Customer Service for your Meter manufacturer for help.

LIMITATIONS

- Do not use with newborns.
- Use each test strip only once. Do not reuse.
- Use only fresh capillary whole blood. Do not use serum or plasma
- Hematocrit means the percentage of red blood cells in your blood. Hematocrit levels under 30% may cause falsely high readings. Hematocrit levels above 55% may cause falsely low readings. Consult your healthcare professional if you do not know your Hematocrit level.
- Use at relative humidity levels between 20% and 80%. Use at temperatures between 43°F and 111°F (6 °C to 44°C).
- Do not use at altitudes above 9,945 feet (3,031 meters).
- Interferences: Abnormally high concentrations of L-dopa, ascorbic acid, acetaminophen, uric acid and gentistic acid may cause falsely high results.
- For nominal glucose levels of 30 mg/dl (1.7 mm/L) interferences occur for Ldopa at concentrations of >3.0 mg/dl in all three meters claimed; for acetaminophen at concentrations >7.5 mg/dl in all three meters claimed; for uric acid at concentrations >5.0 mg/dl in all three meters claimed; and for gentisic acid at concentrations >7.5 mg/dl in all three meters claimed. Levels seen in normal blood or with normal therapeutic concentrations do not significantly affect results.
- Lipemic samples: Cholesterol levels up to 758 mg/dl and triglycerides up to 3000 mg/dl do not affect results. Grossly lipemic samples have not been evaluated. Do not test such samples with these test strips.

INFECTION CONTROL

Treat all patient samples and materials they contact as biohazards. Use universal blood handling precautions. Dispose of all materials as per local regulations.

CAUTION: To reduce the chance of infection:

- Do not share a lancet or lancing device.
- Use lancets only once.
- Always use a new, sterile lancet.
- Keep Meter and lancing device clean.
- Wash testing sites with soap and water before testing.

TEST PRINCIPAL

Glucose in blood combines with an enzyme in the test strip. This produces an electric current in the Meter in proportion to the glucose level. The Meter converts the current flow into a glucose reading on the Meter. The GenUltimate® test strip gives results calibrated to plasma. This allows direct comparison with laboratory results.

REAGENT COMPOSITION

Each strip contains: ≤ 2 IU of Glucose Oxidase (Aspergillus niger), ≤ 1 mg potassium ferricyanide, and non-reactive ingredients.

PERFORMANCE CHARACTERISTICS

Specificity: Test strips measure D-glucose. They do not react to other blood sugars.

Measurement range: 20 – 600 mg/dl (1.1 – 33.3 mm/L)

Precision: Precision was evaluated with six glucose levels in whole blood and three levels of control solution. Results show strip-to-strip variability in blood tests of 3.2% or less.

Precision Test	Test Sample		CV
Within Run	Blood	42 mg/dl (2.3 mmol/L)	3.2%
		84 mg/dl (4.7 mmol/L)	1.9%
		134 mg/dl (7.4 mmol/L)	2.1%
		233 mg/dl (12.9 mmol/L)	1.8%
		384 mg/dl (21.3 mmol/L)	1.7%
		493 mg/dl (27.4 mmol/L)	2.2%
Total	Control	Level 1 (40 mg/dl) (2.2 mmol/L)	4.3%
		Level 2 (118 mg/dl) (6.5 mmol/L)	2.5%
		Level 3 (454 mg/dl) (25.1 mmol/L)	2.4%

Accuracy

The accuracy of the GenUltimate® Test Strip when used with the OneTouch® Ultra®, Ultra®2, and UltraMini® meter was evaluated at one clinical center. Blood glucose meter results from 152 persons with diabetes were compared with laboratory reference instrument results (YSI Model 2300D Glucose Analyzer.) The results are shown below:

METER	Within ± 0.28 mM/L (± 5 mg/dL)	Within ± 0.56 mM/L (± 10 mg/dL)	Within ± 0.83 mM/L (± 15 mg/dL)
UltraMini®	79%, 22/28	100%, 28/28	100%, 28/28
OneTouch® Ultra®	83%, 15/18	100%, 18/18	100%, 18/18
Ultra®2	78%, 18/23	100%, 23/23	100%, 23/23

METER	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
UltraMini®	46%, 474/1036	77%, 800/1036	95%, 980/1036	99%, 1029/1036
OneTouch® Ultra®	45%, 353/740	77%, 567/740	94%, 694/740	99%, 736/740
Ultra®2	49%, 362/739	79%, 584/739	95%, 699/739	99%, 733/739

	YSI < 75 mg/dL (< 4.2 mM/L)			YSI > 75 mg/dL (> 4.2 mM/L)			
	Within 5 mg/dL (0.3 mM/L)	Within 10 mg/dL (0.6 mM/L)	Within 15 mg/dL (0.8 mM/L)	Within 5%	Within 10%	Within 15%	Within 20%
UltraMini®							
Finger	75%, 9/12	100%, 12/12	100%, 12/12	46%, 204/444	77%, 341/444	94%, 416/444	99%, 441/444
Palm	63%, 5/8	100%, 8/8	100%, 8/8	50%, 147/296	84%, 248/296	96%, 284/296	99%, 293/296
Arm	100%, 8/8	100%, 8/8	100%, 8/8	42%, 123/296	71%, 211/296	95%, 280/296	100%, 295/296
Ultra®							
Finger	88%, 7/8	100%, 8/8	100%, 8/8	41%, 120/296	74%, 218/296	93%, 276/296	99%, 294/296
Palm	60%, 3/5	100%, 5/5	100%, 5/5	54%, 120/222	82%, 181/222	93%, 207/222	98%, 218/222
Arm	100%, 5/5	100%, 5/5	100%, 5/5	43%, 95/222	76%, 168/222	95%, 211/222	100%, 221/222
Ultra®2							
Finger	75%, 6/8	100%, 8/8	100%, 8/8	46%, 135/296	77%, 229/296	95%, 281/296	99%, 293/296
Palm	88%, 7/8	100%, 8/8	100%, 8/8	55%, 121/221	83%, 183/221	95%, 209/221	100%, 220/221
Arm	71%, 5/7	100%, 7/7	100%, 7/7	48%, 105/222	77%, 172/222	94%, 209/222	99%, 220/222

This study shows that the GenUltimate® Test Strip used with the OneTouch® Ultra®, Ultra®2 and UltraMini® meters gives results similar to a laboratory method.

REFERENCES

1. American Diabetes Association Standards of Medical Care in Diabetes – 2012, Diabetes Care Vol. 35; Suppl. 1:S11-S63).

CUSTOMER SERVICE

It is our goal to provide you with accurate glucose testing products and exceptional customer service. If you are not satisfied with this product, or for any other reason wish to reach our Customer Service representatives, please call Customer Service at 1-844-874-2762 (24 hours/day; 7 days/week). If you need help at other times, please call your healthcare professional.

GenUltimate® test strips are a product of PharmaTech Solutions, Inc. and are not manufactured, distributed, endorsed, approved by, nor associated with Lifescan®, Inc., a Johnson & Johnson® Company, manufacturers and distributors of the OneTouch® Ultra® Family of Meters and OneTouch® Ultra® test strips.

GenUltimate® Test Strips are manufactured for and distributed by:
PharmaTech Solutions, Inc. Westlake Village, CA 91361 USA

Rev Date: 06/2016 Rev. J

*Gen*Ultimate!® Test Strips – Supplemental Materials

INTENDED USE

Genstrip® (and Genstrip50® and GenUltimate! ®) Test Strips with calibration codes 4, 10, and 13 are for use with OneTouch® Ultra®, Ultra®2, and UltraMini® meters. They are used to quantitatively measure glucose in fresh capillary whole blood samples taken from the finger, forearm or palm. Testing is done outside the body (in vitro diagnostic use). They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control. The system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Four large scientific studies completed by a third party in a laboratory environment demonstrate that the Ultra® Family of meters purchased prior to July 2010 and then at four different times through July 2016, show that Genstrip®50 test strips and the same test strip manufactured under the trade name GenUltimate!® test strips performed statistically the same during large samplings completed first in the Genstrip clinical trials in June 2010 and in large samplings completed in 2013, 2014, 2015 and 2016. The studies completed in 2013, 2014, 2015 and 2016 have not been reviewed by the FDA. You may review these studies at www.pharmatechdirect.com/studies.

The results of those studies are summarized below.

OBJECTIVE

To demonstrate that OneTouch® meters (Ultra®, Ultra®2 and UltraMini®) which were manufactured after July 2010 are equivalent, in terms of their reported glucose responses, to meters which were manufactured before August 2010.

MATERIALS

Control Solutions (low, medium and high)

Meters*:

- 2010 OneTouch® Ultra®
  Pre-2010 UltraMini®
- 2013 OneTouch® UltraMini®
  2013 OneTouch® Ultra®2
- 2014 OneTouch® UltraMini®
  2014 OneTouch® Ultra®2
- 2015 OneTouch® UltraMini®
  2015 OneTouch® Ultra®2
- 2016 OneTouch® UltraMini®
  2016 OneTouch® Ultra2®

GenStrip®, GenStrip50®, and GenUltimate! ® sensors**

OneTouch® Ultra® sensors**

*see table "Meter Serial Numbers & Manufacturing Dates"

**see table "Sensor Lot Information"

PROTOCOL

a. Locate meters where testing can be done efficiently (e.g. flat surfaces, sufficient space, controlled temperature, stable humidity)
b. Control Testing
   i. Locate randomly all meters on the testing surface.
   ii. Identify a single vial of 50 sensors.
   iii. Set meters to the CODE that is appropriate for the lot of sensors being tested.
   iv. Inoculate each sensor with low control solution using transfer pipette
   v. Record results.
   vi. Repeat process using a single vial until two sets of replicates or 40 sensors are tested. Introduce a new vial of product from the same lot and repeat the process. This overall process should be repeated for a total equal to or exceeding 100 results per meter date.
c. Whole Blood Testing
   i. Repeat steps i through iii in section b.
   ii. Acquire enough venous blood to perform at a minimum 2,304 replicates and to be able to adjust the blood's hematocrit and glucose level.
   iii. Adjust glycolyzed blood to 40-42% HCT.
   iv. Adjust glucose concentration to 90 mg/dL (80-100 mg/dL).
   v. Within 20 minutes of accepting the blood spike, inoculate sensors in each meter to acquire as many replicates as is possible. Use the same strategy as in Part b with respect to changing vials.
   vi. Repeat steps iv through v with blood adjusted to 200mg/dL (180-220 mg/dL).
   vii. Repeat steps iv through v with blood adjusted to 375mg/dL (360 – 410 mg/dL).

RESULTS

The results from each sensor were placed in a spreadsheet. Analysis for equivalency was performed using MiniTab 16. The descriptive results for each condition are displayed in the table "Detailed Results."

STATISTICAL ANALYSIS

Student t-test using a 95% confidence value was used to evaluate each pair of meter type across different test solutions. Reported t values and P values are used to reject or accept the null hypothesis. See table "Detailed Statistical Analysis."

SUMMARY

These studies were designed to determine if meters which were manufactured in the years following 2010 performed equivalently to meters which were manufactured before August 2010. Meters were tested using GenStrip®, GenStrip50®, and GenUltimate!® sensors and four test fluids (low control solution and 3 whole bloods [levels over a range of 90 to 400 mg/dL glucose concentrations]). Statistical analysis for each meter pair with a specific test fluid was performed using a Student-t test in MiniTab. **Our results indicate that the P values for the 4 paired evaluations exceed the error tolerance of 0.05 and, therefore, meters are equivalent in terms of the reported glucose values without regard to the meter's manufacturing date through June 2016.**

Table: Meter Serial Numbers & Manufacturing Dates

	Meter	Pre-2010 UltraMini®		2010 Ultra®		2013 UltraMini®		2013 Ultra®2	
		Serial No.	Mf. Date	Serial No.	Mf. Date	Serial No.	Mf. Date	Serial No.	Mf. Date
2013 Data	1	XFF28CBAR	3/2008	BMXC35BTT	7/2010	DHR211FER	4/2012	FLK004OCY	6/2013
	2	XTV28E3AR	11/2008	BMFC0C4TT	7/2010	DHV84F8ER	4/2012	FLK003BCY	6/2013
	3	WWD457BAR	12/2007	BMFC0BETT	7/2010	DHVA539ER	4/2012	FLK0038CY	6/2013
	4	XTV060CAR	11/2008	BMFC0BBTT	7/2010	DHV42ADER	4/2012	FLK048CCY	6/2013
	5	XBB02E9AR	1/2008	BMFC0BFTT	7/2010	DHV41C9ER	4/2012	FLK005ECY	6/2013
	6			BMFC0C4TT	7/2010				
	7			BMFC0BDTT	7/2010				

	Meter	Pre-2010 UltraMini®		2014 UltraMini®/Ultra®2	
		Serial No.	Mf. Date	Serial No.	Mf. Date
2014 Data	1	XTV2820AR	11/2008	FTV016DCY	11/2013
	2	XDD854AAR	2/2008	FQV45A8ER	9/2013
	3	XTV28E3AR	11/2008	GBN6B16CY	1/2014
	4	XTV056EAR	11/2008	GBN0BA3CY	1/2014
	5	XTV0582AR	11/2008	FQV45AAER	9/2013
	6	XTV060BAR	11/2008	FQV45B7ER	9/2013
	7	XTV28FFAR	11/2008	FQV45B1ER	9/2013
	8	XBB8385AR	1/2008	GBN0B5DCY	1/2014
	9	XTV060CAR	11/2008	FQV06B3ER	9/2013
	10	XTV4362AR	11/2008	GBN6AE1CY	1/2014

	Meter	Pre-2010 UltraMini®		2015 UltraMini®/Ultra®2	
		Serial No.	Mf. Date	Serial No.	Mf. Date
2015 Data	1	WVQ473FAR	Dec-07	DHV84F8ER	Apr-12
	2	WWD457BAR	Dec-07	DHP80EFER	Apr-12
	3	XBB02E9AR	Jan-08	FQV06B3ER	Sep-13
	4	XBB8323AR	Jan-08	FQV45B1ER	Sep-13
	5	XBC0463AR	Jan-08	FQV45B7ER	Sep-13
	6	XBCC1BCAR	Jan-08	GBN6B16CY	Jan-14
	7	XCH8573AR	Jan-08	GBN0BA3CY	Jan-14
	8	XDFC46FAS	Feb-08	FKV048CCY	Jun-13
	9	XFF28CBAR	Mar-08	FKV6452CY	Jun-13
	10	XTV0582AR	Nov-08	GBN6AE1CY	Jan-14
	11	WVQ473FAR	Dec-07	DHV84F8ER	Apr-12

	Meter	Pre-2010 UltraMini®		2016 UltraMini®/Ultra®2	
		Serial No.	Mf. Date	Serial No.	Mf. Date
2016 Data	1	WVQ473FAR	Dec-07	FVM2340ER	Nov -13
	2	XTVOSOCAR	Nov-08	FVM2350ER	Nov -13
	3	XTV060BAR	Nov-08	FVM035FER	Nov -13
	4	XTV0594AR	Nov-08	FVM42C9ER	Nov -13
	5	XBC0463AR	Jan-08	FVM2347ER	Nov-13
	6	XTV28EDAR	Nov-08	GJH6408CY	May-14
	7	XCH8573AR	Jan-08	GMP522CY	Jul-14
	8	XTV282FAR	Nov-08	GNG0569CY	Jul-14
	9	XBCCIBCAR	Jan-08	GST6968CY	Oct-14
	10	XTV4362AR	Nov-08	HQS6019EY	Sep-15

Table: Sensor Lot Information

	Sensor	Lot #	Calibration Code	Expiration Date	Control Solution used to test
2013 Data	GenStrip®	115A	13	11/14	Low
	GenStrip®	116A	13	11/14	Medium
	GenStrip®	117A	13	11/14	High
	Ultra® Blue	3492129	25	1/15	High
	Ultra® Blue	3490870	25	1/15	High
	Ultra® Blue	3487121	25	1/15	High
	Ultra® Blue	3461200	25	11/14	Low
	Ultra® Blue	3464735	25	11/14	Low

Year	Sensor	Lot #	Calibration Code	Expiration Date	Control Solution used to test
2014	GenStrip®	0143	10	11/15	Low
2015	GenStrip50®	168A	4	8/2017	Low
2016	GenStrip50®	AA135	4	3/2018	Low

Table: Detailed Results

	Meter	Control Test Fluid	Sensor	N	Mean Glucose (mg/dL)	SD (mg/dL)	SE Mean
2013 Data	Pre-2010 UltraMini®	Low	GenStrip®	150	53.7[2]	1.8	0.15
	2013 UltraMini®	Low	GenStrip®	150	53.3	2.1	0.17
	2010 Ultra®	Low	GenStrip®	150	52.7	2.1	0.17
	2013 Ultra®	Low	GenStrip®	150	53.3	1.8	0.15
	Pre-2010 UltraMini®	Medium	GenStrip®	150	221.0	6.0	0.49
	2013 UltraMini®	Medium	GenStrip®	150	220.2	6.4	0.52
	2010 Ultra®	Medium	GenStrip®	150	218.4	5.8	0.47
	2013 Ultra®	Medium	GenStrip®	150	218.9	6.5	0.53
	Pre-2010 UltraMini®	High	GenStrip®	300	370.0	16.1	0.9
	2013 UltraMini®	High	GenStrip®	299[1]	368.9	16.7	1.0
	2010 Ultra®	High	GenStrip®	150	364.7	13.9	1.1
	2013 Ultra®	High	GenStrip®	150	364.6	13.5	1.1
	Pre-2010 UltraMini®	Low	Ultra®	100	65.7	1.7	0.17
	2013 UltraMini®	Low	Ultra®	100	65.3	1.9	0.19
	Pre-2010 UltraMini®	High	Ultra®	100	409.6	11.1	1.1
	2013 UltraMini®	High	Ultra®	100	407.5	11.7	1.2

	Meter	Test Fluid	N	Mean Glucose (mg/dL)	SD (mg/dL)	SE Mean
2014 Data	Pre-2010 UltraMini®	Low Control	140	63.7	3.0	0.25
	2014 UltraMini®/Ultra®2	Low Control	140	63.5	2.8	0.24
	Pre-2010 UltraMini®	Low WB	140	99.3	4.8	0.41
	2014 UltraMini®/Ultra®2	Low WB	140	98.9	4.4	0.38
	Pre-2010 UltraMini®	Medium WB	140	200.0	7.7	0.65
	2014 UltraMini®/Ultra 2	Medium WB	140	199.3	8.48	0.72
	Pre-2010 UltraMini®	High WB	140	356.3	19.1	1.6
	2014 UltraMini®/Ultra®2	High WB	140	354.9	17.9	1.5

	Meter	Test Fluid	N	Mean Glucose (mg/dL)	SD (mg/dL)
2015 Data	Pre-2010 UltraMini®	Low Control	150	52.9	3.5
	2015 UltraMini®/Ultra®2	Low Control	150	52.9	3.9
	Pre-2010 UltraMini®	Low WB	140	113.4	4.9
	2015 UltraMini®/Ultra®2	Low WB	140	114.2	4.5
	Pre-2010 UltraMini®	Medium WB	140	241.8	8.5
	2015 UltraMini®/Ultra 2	Medium WB	140	240.9	8.4
	Pre-2010 UltraMini®	High WB	140	450.9	11.1
	2015 UltraMini®/Ultra®2	High WB	140	450.9	14.5

	Meter	Test Fluid	N	Mean Glucose (mg/dL)	SD (mg/dL)	SE Mean
2016 Data	Pre-2010 UltraMini®	Low Control	150	62.3	1.9	0.16
	2016 UltraMini®/Ultra®2	Low Control	150	62.2	1.9	0.16
	Pre-2010 UltraMini®	Low WB	140	106.5	3.7	0.23
	2016 UltraMini®/Ultra®2	Low WB	140	106.0	3.5	0.29
	Pre-2010 UltraMini®	Medium WB	140	216.7	8.6	0.73
	2016 UltraMini®/Ultra 2	Medium WB	140	216.3	6.8	0.58
	Pre-2010 UltraMini®	High WB	140	413.9	16.0	1.4
	2016 UltraMini®/Ultra®2	High WB	140	415.4	16.9	1.4

[1] One sensor exhibited an E-5 error.

[2] For this experiment the results for meters BMFC0BBTT and BMFFC0BFTT were found to be statistically different from the results for other 3 meters. Two new meters (BMFC0C4TT and BMFC0BDTT) were introduced and their results were used for this level only.

Table: Detailed Statistical Analysis

	Meter	Control Test Fluid	Sensor	Difference	t value	P value	DF
2013 Data	UltraMini®	Low	GenStrip®	0.4	1.64	0.102	292
	Ultra®	Low	GenStrip®	-0.4	-1.74	0.083	290
	UltraMini®	Medium	GenStrip®	0.8	1.09	0.279	296
	Ultra®	Medium	GenStrip®	-0.6	-0.78	0.438	293
	UltraMini®	High	GenStrip®	1.0	0.77	0.433	595
	Ultra®	High	GenStrip®	0.1	0.04	0.966	297
	UltraMini®	Low	Ultra®	0.4	1.44	0.152	195
	UltraMini®	High	Ultra®	2.1	1.29	0.200	197

	Test Fluid	Difference of the Means (mg/dL)	t value	P value	DF
2014 Data	Low Control	0.16	0.45	0.650	276
	Low Whole Blood	0.42	0.76	0.447	276
	Medium Whole Blood	0.64	0.66	0.512	275
	High Whole Blood	1.4	0.63	0.530	276

	Test Fluid	Difference of the Means (mg/dL)	t value	P value	DF
2015 Data	Low Control	0.01	0.02	0.988	294
	Low Whole Blood	-0.8	-1.42	0.158	276
	Medium Whole Blood	0.91	0.91	0.365	277
	High Whole Blood	0.01	0.01	0.993	259

	Test Fluid	Difference of the Means (mg/dL)	t value	P value	DF
2016 Data	Low Control	0.07	0.30	0.762	297
	Low Whole Blood	0.50	1.14	0.256	275
	Medium Whole Blood	-0.62	-0.67	0.505	264
	High Whole Blood	-1.54	-0.78	0.436	277

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