

GenUltimate!® 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.

Six 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 six different times through December 2017, 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, 2016 and 2017. These studies 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

OneTouch® Control Solution (Low, Medium, High, or Normal)

Meters*:

- 2010 OneTouch® Ultra®
- 2014 OneTouch® UltraMini®
- 2016 OneTouch® UltraMini®
- Pre-2010 UltraMini®
- 2014 OneTouch® Ultra*2
- 2016 OneTouch® Ultra*2
- 2013 OneTouch® UltraMini®
- 2015 OneTouch® UltraMini®
- 2017 OneTouch® UltraMini®
- 2013 OneTouch® Ultra*2
- 2015 OneTouch® Ultra*2
- 2017 OneTouch® Ultra*2

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 OneTouch® control solution using transfer pipette
 - v. Record results.
 - vi. Repeat process using a single vial until 2 sets of replicates or 30 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 240 results for post 2010 meters and 120 results for pre-2010 meters.
- c. Whole Blood Testing
 - i. Repeat steps i through iii in section b.
 - ii. Acquire venous blood from a single blood donor using work instruction for Whole Blood Collection W1202.
 - iii. Adjust glycolized blood to 40-42% HCT.
 - iv. Adjust glucose concentration to 90 mg/dL (80-100 mg/dL) or 60 mg/dL (45-70 mg/dL) using work instruction for Preparing and Assaying Whole Blood Samples W1203.
 - 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 (control solution and 3 whole bloods [levels over a range of 60 to 400 mg/dL glucose concentrations]). Statistical analysis for each meter pair with a specific test fluid was performed using a Student-t. **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 December 2017.**

Table: Meter Serial Numbers & Manufacturing Dates

	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	BMFCOCATT	7/2010	DHV84F8ER	4/2012	FLK003BCY	6/2013
	3	WWD457BAR	12/2007	BMFCOBETT	7/2010	DHVA539ER	4/2012	FLK0038CY	6/2013
	4	XTV060CAR	11/2008	BMFCOBETT	7/2010	DHV42ADER	4/2012	FLK048CCY	6/2013
	5	XBB02E9AR	1/2008	BMFCOBFTT	7/2010	DHV41C9ER	4/2012	FLK005ECY	6/2013
	6			BMFCOCATT	7/2010				
	7			BMFCOBETT	7/2010				
2014 Data	Pre-2010 UltraMini®		2014 UltraMini®/Ultra*2						
	1	XTV2820AR	11/2008	FTV016DCY				11/2013	
	2	XDB854AAR	2/2008	FQV45A8ER				9/2013	
	3	XTV28E3AR	11/2008	GBN6B16CY				1/2014	
	4	XTV056EAR	11/2008	GBN0B33CY				1/2014	
	5	XTV0582AR	11/2008	FQV45AAER				9/2013	
	6	XTV060BAR	11/2008	FQV45B7ER				9/2013	
	7	XTV28FFAR	11/2008	FQV45B1ER				9/2013	
	8	XBB835SAR	1/2008	GBN0B5DCY				1/2014	
	9	XTV060CAR	11/2008	FQV06B3ER				9/2013	
10	XTV4362AR	11/2008	GBN6AE1CY				1/2014		
2015 Data	Pre-2010 UltraMini®		2016 UltraMini®/Ultra*2						
	1	WVQ473FAR	Dec-07	DHV84F8ER				Apr-12	
	2	WWD457BAR	Dec-07	DHP80E3ER				Apr-12	
	3	XBB02E9AR	Jan-08	FQV06B3ER				Sep-13	
	4	XB88323AR	Jan-08	FQV45B1ER				Sep-13	
	5	XBC0463AR	Jan-08	FQV45B7ER				Sep-13	
	6	XBCC1BCAR	Jan-08	GBN6B16CY				Jan-14	
	7	XCH8573AR	Jan-08	GBN0B33CY				Jan-14	
	8	XDF46FAS	Feb-08	FKV048CCY				Jun-13	
	9	XF28CBAR	Mar-08	FKV45A2CY				Jun-13	
10	XTV0582AR	Nov-08	GBN6AE1CY				Jan-14		
11	WVQ473FAR	Dec-07	DHV84F8ER				Apr-12		
2016 Data	Pre-2010 UltraMini®		2016 UltraMini®/Ultra*2						
	1	WVQ473FAR	Dec-07	FVM2340ER				Nov-13	
	2	XTV060BAR	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	GN0569CY				Jul-14	
	9	XBCC1BCAR	Jan-08	GST6968CY				Oct-14	
10	XTV4362AR	Nov-08	HQS6019EY				Sep-15		
2017 Data	Meters Purchased for 2017 Study			Meters Purchased prior to July 2010					
	Meter	Serial #	Manu. date	Meter	Serial #	Manu. date			
	UltraMini®	FSL291FER	Oct-13	UltraMini®	XCH8573AR	Jan-08			
	UltraMini®	FSK2037ER	Oct-13	UltraMini®	WWD457BAR	Dec-07			
	UltraMini®	FSL085FER	Oct-13	UltraMini®	XBCC1BCAR	Jan-08			
	UltraMini®	FSK402BER	Oct-13	UltraMini®	XTV4362AR	Nov-08			
	UltraMini®	FSL0883ER	Oct-13	UltraMini®	XTV0582AR	Nov-08			
	Ultra*2	HLF0D11EY	Jun-15						
	Ultra*2	GT00142CY	Oct-14						
	Ultra*2	HLF0370EY	Jun-15						
2018 Data	Meters Purchased for 2018 Study			Meters Purchased prior to July 2010					
	Meter	Serial #	Manu. date	Meter	Serial #	Manu. date			
	UltraMini®	(21)KHN4649ER	04/17	UltraMini®	XCH8573AR	Jan-08			
	UltraMini®	(21)KHP26D4ER	04/17	UltraMini®	WWD457BAR	Dec-07			

	UltraMini®	(21)KHP0755ER	04/17	UltraMini®	XBCC1BCAR	Jan-08
	UltraMini®	(21)KHS008DER	04/17	UltraMini®	XTV4362AR	Nov-08
	UltraMini®	(21)KHS4062ER	04/17	UltraMini®	XTV0582AR	Nov-08
	Ultra*2	(21)JTI6987EY	11/16			
	Ultra*2	(21)JTI698AEY	11/16			
	Ultra*2	(21)JTI09COEY	11/16			
	Ultra*2	(21)JTK6297EY	11/16			
	Ultra*2	(21)JTI09F2EY	11/16			

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
2017	GenStrip50®	AB265			
	GenUltimate!®	AC033			
2018	GenUltimate!®	7001A			

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 ^z	1.8	0.15
	2013 UltraMini®	Low	GenStrip®	150	53.3	2.1	0.17
	2010 Ultra*2	Low	GenStrip®	150	52.7	2.1	0.17
	2013 Ultra*2	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*2	Medium	GenStrip®	150	218.4	5.8	0.47
	2013 Ultra*2	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 ^z	368.9	16.7	1.0
	2010 Ultra*2	High	GenStrip®	150	364.7	13.9	1.1
	2013 Ultra*2	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	
2014 Data	Meter	Test Fluid	N	Mean Glucose (mg/dL)	SD (mg/dL)	SE Mean	
	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		
2015 Data	Meter	Test Fluid	N	Mean Glucose (mg/dL)	SD (mg/dL)	SE Mean	
	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			
2016 Data	Meter	Test Fluid	N	Mean Glucose (mg/dL)	SD (mg/dL)	SE Mean	
	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		
2017 Data	Meter	Test Fluid	N	Mean mg/dL	SD mg/dL	SE Mean	
	Pre-2010 UltraMini®	Control Solution	240	123.9	6.5	0.59	
	2016 UltraMini®/Ultra*2	Control Solution	120	122.9	6.4	0.41	
	Pre-2010 UltraMini®	Blood Level 1	120	90.4	3.7	0.47	
	2016 UltraMini®/Ultra*2	Blood Level 1	60	89.4	3.4	0.31	
	Pre-2010 UltraMini®	Blood Level 2	120	252.8	9.4	1.22	
	2016 UltraMini®/Ultra*2	Blood Level 2	60	251.9	8.6	0.79	
	Pre-2010 UltraMini®	Blood Level 3	120	428.2	15.3	1.98	