Meter Validation Study

January 2017

Background

In July of 2013 the company began replacing its product release testing meters with newer generation meters because the product release testing meters, acquired in July 2010, were showing wear and needed replacement with newer meters. This practice has continued throughout the manufacturing history of GenStrip, GenStrip50 and GenUltimate test strips. All product release testing meters used had been commercially "off the shelf" acquired new and in sealed packages either from retail outlets such as pharmacies or department stores with pharmacies or from on-line diabetic products distributors. As these new meters were acquired, a series of validation studies, conducted by laboratory professionals in a laboratory environment, was initiated to determine whether successive groups of LifeScan OneTouch® Ultra®, Ultra2® and UltraMini® meters performed in a manner equivalent to their earlier acquired counterparts. In all, five detailed validation studies have been completed. The information to be provided in the foregoing is the fifth of the five validation studies. This fifth validation study in January 2017.

1. Objective

To demonstrate that OneTouch® Ultra® family meters which were manufactured after July, 2010 are equivalent, in terms of their reported glucose responses, to the same family of meters which were manufactured before August, 2010. For our initial Meter Verification Study meters were purchased in August, 2013 for our testing. For the second Meter Validation Study meters were purchased in January, 2014. For the third Meter Validation Study meters were purchased in May and June, 2014. The fourth Meter Validation Study meters were purchased in May, 2016. The fifth Meter Validation Study meters were purchased in December, 2016.

2. Materials

a. OneTouch® Normal Control Solution
b. Meters: OneTouch® Pre-2010 UltraMini® (5 meters); OneTouch® December 2016 UltraMini® and OneTouch® December 2016 Ultra®2 (5 meters each)
c. GenStrip50 sensors: Vials of 50s from 1 lot: Lot # AB265
GenUltimate! Sensors: Vials of 50s from 1 lot: Lot # AC033

Meter Serial Numbers

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	GTD0142CY	Oct-14			
Ultra®2	HLF0370EY	Jun-15			
Ultra®2	HLF6BBFEY	Jun-15			
Ultra®2	HLF6B70EY	Jun-15			

3. Protocol | Evaluating OneTouch® Meter Equivalency WI004/ WI204

a. Control Solution Testing
   i. Locate randomly the 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.
   v. Record results on data collection form.
   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 of 240 results for post 2010 meters and 120 results for pre-2010 meters.

b. Whole Blood Testing
   i. Repeat steps i. through iii. in step a.
   ii. Acquire venous blood from a single blood donor using work instruction for Whole Blood Collection WI002/WI202.
   iii. Adjust glucose concentration to 60 mg/dL (45-70 mg/dL) using work instruction for Preparing and Assaying Whole Blood Samples WI003/WI203.
   iv. Within 20 minutes of accepting the blood spike, inoculate sensors in each meter using a single vial until two sets of replicates or 20/30 sensors are tested. Introduce a new vial of product from the same lot and repeat the process as many times as possible within the 20 minutes.
   v. Repeat steps iii. and iv. with blood adjusted to 200 mg/dL (180-220 mg/dL).
   vi. Repeat steps iii. and iv. with blood adjusted to 375 mg/dL (360-410 mg/dL).

4. Results

The results from each sensor were placed in an Excel spreadsheet. The descriptive results for each condition are displayed in the following tables.

	Meter	Test Fluid	N	Mean mg/dL	SD mg/dL	SE Mean
GenStrip50	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
	2016 UltraMini®/Ultra®2	Blood Level 3	60	425.2	16	1.46
GenUltimate!	**Meter**	**Test Fluid**	**N**	**Mean mg/dL**	**SD mg/dL**	**SE Mean**
	Pre-2010 UltraMini®	Control solution	240	135.9	5.1	0.46
	2016 UltraMini®/Ultra®2	Control solution	120	135.3	4.5	0.29
	Pre-2010 UltraMini®	Blood Level 1	110	77.2	7.4	0.99
	2016 UltraMini®/Ultra®2	Blood Level 1	55	74.9	8.3	0.79
	Pre-2010 UltraMini®	Blood Level 2	120	286.1	7.3	0.94
	2016 UltraMini®/Ultra®2	Blood Level 2	60	284.1	8.6	0.78
	Pre-2010 UltraMini®	Blood Level 3	120	460.2	19.7	2.5
	2016 UltraMini®/Ultra®2	Blood Level 3	60	454.7	17.2	1.5

5. 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.

	Test Fluid	Difference of the Means (mg/gL)	T value	P value	DF
GenStrip50	Control Solution	-0.94	-1.3	0.19	236
	Blood Level 1	-1	-1.77	0.08	111
	Blood Level 2	-0.8	-0.55	0.58	109
	Blood Level 3	-2.98	-1.2	0.22	123
GenUltimate!	**Test Fluid**	**Difference of the Means (mg/gL)**	**T value**	**P value**	**DF**
	Control Solution	-0.58	-1.04	0.29	216
	Blood Level 1	-2.27	-1.79	0.07	121
	Blood Level 2	-1.99	-1.61	0.11	135
	Blood Level 3	-5.47	-1.82	0.07	105

6. Summary

This experiment was designed to determine if meters which were purchased commercially from retail vendors “off the shelf” in December 2016 performed equivalently to meters which were purchased in the same manner prior to August, 2010. Meters were tested using GenStrip50 sensors (Lot AB265), GenUltimate! Sensors (Lot AC033), and four test fluids (OneTouch® control solution and 3 whole bloods levels over a range of 60 to 410 mg/dL glucose concentrations. Statistical analysis for each meter pair with a specific test fluid was performed using a Student-t test. 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.