Meter Validation Study

January 2018

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, six detailed validation studies have been completed. The information to be provided in the foregoing is the sixth of the six validation studies. This sixth validation study was initiated in December 2017 and completed in 2018.

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. The sixth Meter Validation Study meters were purchased in December 2017.

2. **Materials**
   a. OneTouch® Normal Control Solution
   b. Meters: OneTouch® Pre-2010 UltraMini® (5 meters); OneTouch® 2017 UltraMini® and OneTouch® December 2017 Ultra®2 (5 meters each)
   c. GenUltimate! Sensors: Vials of 50s from 1 lot: Lot # 7001A

Meter Serial Numbers

Meters Purchased for 2017 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)JTJ6987EY	11/16			
Ultra®2	(21)JTJ698AEY	11/16			
Ultra®2	(21)JTJ09C0EY	11/16			
Ultra®2	(21)JTK6297EY	11/16			
Ultra®2	(21)JTJ09F2EY	11/16			

3. Evaluating OneTouch® Meter Equivalency WI204 Protocol

a. OneTouch® 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 WI202.
   iii. Adjust glucose concentration to 60 mg/dL (45-70 mg/dL) using work instruction for Preparing and Assaying Whole Blood Samples 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 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
Pre-2010 UltraMini®	Control solution	120	147.5	2.5
2017 UltraMini®/Ultra®2	Control solution	240	148.1	2.8
Pre-2010 UltraMini®	Blood Level 1	50	86.0	1.7
2017 UltraMini®/Ultra®2	Blood Level 1	100	86.3	2.2
Pre-2010 UltraMini®	Blood Level 2	50	222.0	5.5
2017 UltraMini®/Ultra®2	Blood Level 2	100	224.7	6.7
Pre-2010 UltraMini®	Blood Level 3	50	395.1	9.2
2017 UltraMini®/Ultra®2	Blood Level 3	100	400.0	13.6

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
Control Solution	0.5	1.84	0.06	264
Blood Level 1	0.3	0.98	0.32	122

Blood Level 2	1.1	1.16	0.24	111
Blood Level 3	3.6	1.96	0.05	130

6. Summary

This experiment was designed to determine if meters which were purchased commercially from retail vendors "off the shelf" in late 2017 performed equivalently to meters which were purchased in the same manner prior to August 2010. Meters were tested using GenUltimate! Sensors (Lot 7001A) 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 or are equal to 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.