

White Paper, **One Drop** | Chrome  
Blood Glucose Monitoring System  
Analytical Performance



# Table of Contents

Executive Summary	3
Precision	4
Repeatability (Within-Run Precision)	4
Intermediate Precision (Day-to-Day Precision)	5
System Accuracy	6
Hematocrit	8
Chemical Interference	9
User Performance Evaluation	11
Technical and Analytical Information	12
References	13

## Executive Summary

The One Drop | Chrome Blood Glucose Monitoring System is a Bluetooth-connected blood glucose monitoring system that, with the One Drop | Mobile app, allows for the seamless capture, analysis and sharing of blood glucose results. This document summarizes the analytical performance of the One Drop | Chrome Blood Glucose Monitoring System, which was cleared by FDA in November 2016.

## Precision

### Repeatability (Within-Run Precision)

The One Drop | Chrome Blood Glucose Monitoring System within run precision was evaluated using venous blood samples depleted or spiked to five different glucose concentrations across the system measuring range (30–50 mg/dL, 51–110 mg/dL, 111–150 mg/dL, 151–250 mg/dL, 251–400 mg/dL). Each sample was tested on three lots of test strips using 12 meters per test strip lot. Ten replicates were tested per meter, test strip lot and glucose concentration.

### Results

Glucose Concentration, (mg/dL)	Strip Lot	n	Mean (mg/dL)	SD (mg/dL)	CV (%)
30–50	1	118	34.8	2.4	6.9
	2	119	31.3	1.6	5.3
	3	119	30.6	2.6	8.5
	Combined			2.9	9.0
51–110	1	120	100.8	3.2	3.2
	2	120	96.4	3.9	4.0
	3	120	96.9	4.0	4.1
	Combined			4.2	4.3
111–150	1	120	132.9	2.6	2.0
	2	120	129.3	4.2	3.3
	3	120	128.5	3.9	3.0
	Combined			4.1	3.2
151–250	1	120	220.1	6.5	2.9
	2	120	221.1	7.7	3.5
	3	120	229.5	5.0	2.2
	Combined			7.7	3.5
251–400	1	120	388.0	9.9	2.5
	2	120	379.9	16.3	4.3
	3	120	380.4	17.3	4.6
	Combined			15.3	4.0

## Intermediate Precision (Day-to-Day Precision)

The One Drop | Chrome Blood Glucose Monitoring System intermediate precision was established by evaluating three glucose control solutions, with multiple meters (10 meters) over multiple days (10 days) using three different operators and three lots of test strips.

### Results

Test Strip Lot 1			
Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	57.1	1.6	2.8
Level 2	134.0	3.4	2.6
Level 4	343.5	8.5	2.5

Test Strip Lot 2			
Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	57.8	2.2	3.7
Level 2	137.9	2.9	2.1
Level 4	345.5	8.8	2.6

Test Strip Lot 3			
Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	57.1	1.8	3.1
Level 2	134.3	3.1	2.3
Level 4	342.5	7.4	2.2

## System Accuracy

The One Drop | Chrome Blood Glucose Monitoring System accuracy was evaluated using 124 whole blood samples (117 obtained by fresh capillary finger stick and 7 altered blood samples) ranging in concentration from 35.9–539.8 mg/dL. Three lots of test strips were tested in the study. Blood glucose results obtained with the meter were compared to the plasma glucose results obtained using the YSI Model 2300 Glucose Analyzer.

## Results

The difference between each individual BGM reading and its corresponding YSI 2300 STAT Plus plasma glucose reference concentration for all the three test strip lots is shown in the system accuracy difference plot, Figure 1. The study concluded that the One Drop | Chrome Blood Glucose Monitoring System demonstrates good system accuracy, with:

- 97.5% of readings falling within 15% of reference concentrations for glucose concentrations  $\geq 75$  mg/dL, and
- 99.0% of readings falling within 15 mg/dL of reference concentrations for glucose concentrations  $< 75$  mg/dL.

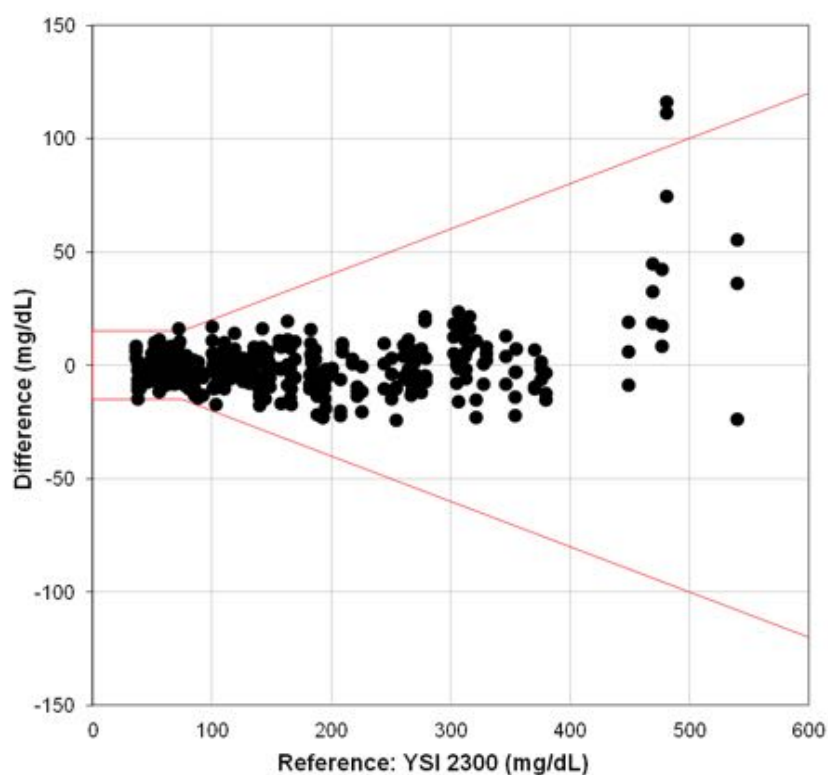


Figure 1: System accuracy plot for One Drop | Chrome BGMS glucose vs. YSI 2300 plasma glucose concentration. Data shown is from three test strip lots. Area inside the solid lines represents minimum acceptable accuracy from ISO 15197:2003.

Table 1: System accuracy results for glucose concentrations &lt;75 mg/dL

Lot	Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL
<b>1</b>	19/32 (59.4%)	29/32 (90.6%)	31/32 (96.9%)
<b>2</b>	21/32 (65.6%)	30/32 (93.8%)	32/32 (100.0%)
<b>3</b>	16/32 (50.0%)	30/32 (93.8%)	32/32 (100.0%)
<b>Combined</b>	56/96 (58.3%)	89/96 (92.7%)	95/96 (99.0%)

Table 2: System accuracy results for glucose concentrations  $\geq 75$  mg/dL

Lot	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
<b>1</b>	63/92 (68.5%)	87/92 (94.6%)	91/92 (98.9%)	92/92 (100.0%)
<b>2</b>	57/92 (62.0%)	81/92 (88.0%)	88/92 (95.7%)	91/92 (98.9%)
<b>3</b>	47/92 (51.1%)	81/92 (88.0%)	90/92 (97.8%)	91/92 (98.9%)
<b>Combined</b>	167/276 (60.5%)	249/276 (90.2%)	269/276 (97.5%)	274/276 (99.3%)

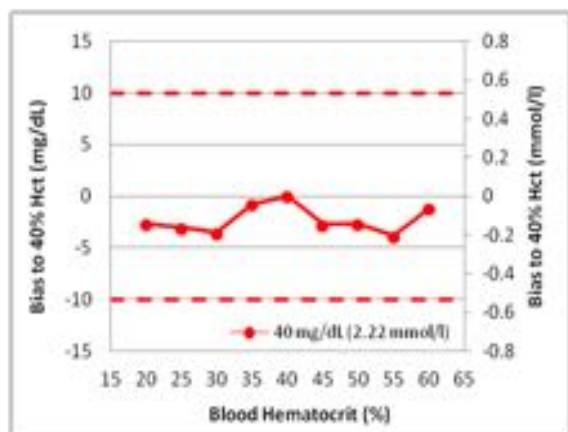
## Hematocrit

The One Drop | Chrome Blood Glucose Monitoring System was tested with venous whole blood samples at three glucose concentrations (40, 125, and 350 mg/dL) and nine hematocrit levels (20, 25, 30, 35, 40, 45, 50, 55, 60%). Each sample was measured with ten meters and three test strip lots for a total of 30 replicates, and with the YSI 2300 reference method.

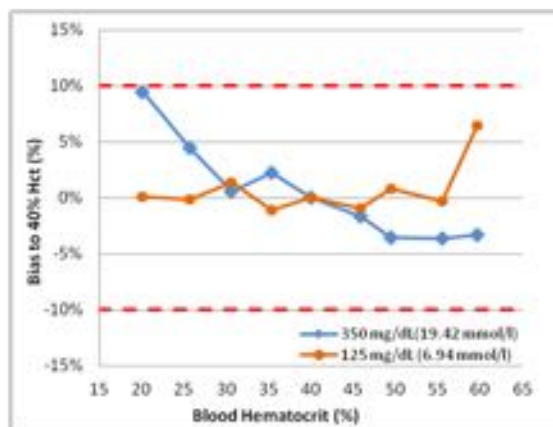
### Results

Mean bias in meter results at each hematocrit and nominal hematocrit (40%) at each glucose and hematocrit level is shown in the graph below (Figure 2). Across all strip lots, 99.9% of the meter readings fell within  $\pm 15$  mg/dL or  $\pm 15\%$  of the YSI reference glucose measurement. Results from the study support claimed hematocrit range of 20–60%.

Acceptance Criteria	Result (across 3 strip lots)
For glucose concentrations <100 mg/dL, the mean bias in meter results between each hematocrit and nominal hematocrit (40%) will not exceed $\pm 10$ mg/dL.	Less than $\pm 5$ mg/dL
For glucose concentrations $\geq 100$ mg/dL, the mean bias in meter results between each hematocrit and the nominal hematocrit (40%) will not exceed $\pm 10\%$ .	Less than $\pm 9.5\%$



(a)



(b)

Figure 2: Mean Bias for Glucose Level 1 (a) and Levels 2 & 3 (b)



## Chemical Interference

To assess potential interference, three venous whole blood samples (with glucose concentrations 75, 120, 300 mg/dL) were spiked with potentially interfering substances at high (toxic/pathological) levels. Study design and analysis followed CLSI EP7-A2 guidance (1). Each sample was measured on ten meters using three strip lots for a total of 30 replicates per sample. The effect of the potential interferent was assessed by calculating the average difference in glucose readings between the test sample with high interferent concentration and the control sample with low/no interferent. Significant interference was defined as a bias in readings between the tested and control sample of  $>\pm 10$  mg/dL for glucose concentrations  $<100$  mg/dL or a bias of  $\geq\pm 10\%$  for glucose concentrations  $>100$  mg/dL.

### Results

The performance of the One Drop | Chrome Blood Glucose Monitoring System with respect to the chemical interference requirements is summarized in the table below. Among the 35 interferents tested, only ascorbic acid exhibited potential interference. Therefore, a dose response study was performed and the upper limit for no significant interference was estimated at 3 mg/dL. The following limitation has been added to the labeling: "If you are taking Vitamin C (ascorbic acid) at large doses you may get inaccurate results with this system."

Interferent	Highest concentration tested with no significant interference (mg/dL)	Interferent	Highest concentration tested with no significant interference (mg/dL)
Acetaminophen	20	Lactose	10
Ascorbic acid	3	L-DOPA	4
Bilirubin, conjugated	29	Maltose	278
Bilirubin, Free	20	Mannitol	53
Caffeine	6	Methyl-DOPA	1.5
Ceftriaxone	97	PAM iodide	80
Cholesterol	600	Pralidoxime chloride	52
Creatinine	5	Salicylate	60
Dopamine	0.09	Sorbitol	600
EDTA	0.1	Sucrose	20
Fructose	18	Tolazamide	5
Galactose	120	Tolbutamide	64
Gentisic acid	1.8	Triglyceride	3300
Glutathione	92	Uric acid	23.5

Hemoglobin	200	Xylitol	60.9
Heparin	1.9	Xylose	120
Ibuprofen	50	$\alpha$ -Lipoic acid	2
Icodextrin	1094		

## User Performance Evaluation

A lay user study was conducted to assess the accuracy and usability of the blood glucose meter in the hands of the intended user. The study was conducted using 100 lay users with Type 1 or Type 2 diabetes, using one lot of test strips, to evaluate that the intended users are able to obtain accurate glucose measured values when operating the blood-glucose monitoring system, given only the instructions and training materials routinely provided with the system. The blood glucose results obtained from the finger by the subjects were compared to the YSI 2300 reference results.

### Results

The finger stick blood glucose results obtained by the user with the One Drop | Chrome Blood Glucose Monitoring System were compared against the reference plasma glucose determined by YSI 2300. The system accuracy difference plot is shown in Figure 3 .

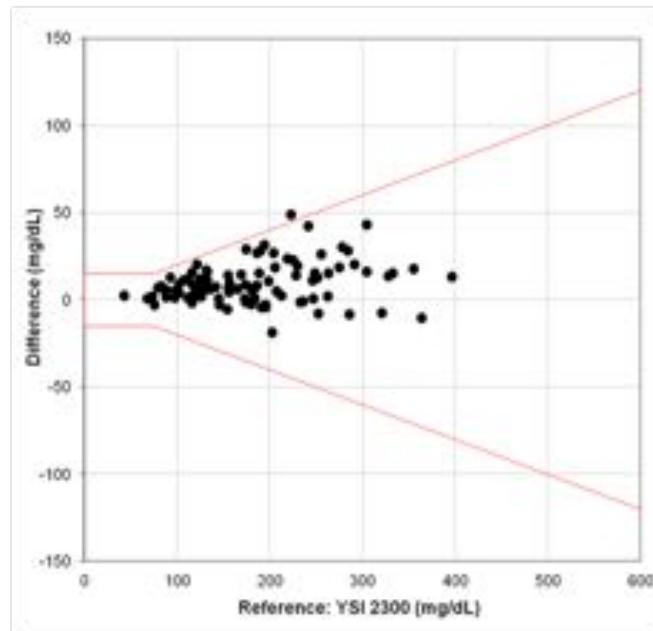


Figure 3: System accuracy plot – One Drop | Chrome BGMS glucose vs. YSI 2300 plasma glucose concentration (User Study)

The total number of acceptable results, i.e., individual glucose readings falling within  $\pm 15$  mg/dL of the measured values of the manufacturer’s measurement procedure at glucose concentrations  $< 75$  mg/dL and within  $\pm 15\%$  at glucose concentrations  $\geq 75$  mg/dL, for all glucose concentrations was 99/100 (99%).

For glucose concentrations  $< 75$  mg/dL

Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL
4/4 (100%)	4/4 (100%)	4/4 (100%)

For glucose concentrations  $\geq 75$  mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
48/96 (50%)	77/96 (80%)	91/96 (95%)	95/96 (99%)

## Technical and Analytical Information

Specifications of the One Drop   Chrome Blood Glucose Monitoring System	
Measurement principle	Glucose oxidase; indication by Dynamic Electrochemistry™
Measurement range	20–600 mg/dL
Calibration	Plasma Equivalent
Measurement duration	5 seconds
Operating temperature range	50°–104°F
Coding test strips	No coding required
Sample volume	0.5 $\mu$ l
Strip shelf life	21 months (stored at 46° to 86°F) unopened and 180 days after first opening
Hematocrit range	20–60%
Maximum altitude for measurement	10,000 ft.
Operating Humidity	10% to 90%
Sample Material	Capillary whole blood

### Test Principle

The One Drop test strip contains glucose oxidase (GOx) enzyme with a redox chemical mediator that produces an electrochemical signal in proportion to the glucose concentration in the blood sample. The blood glucose meter measures this signal, using dynamic electrochemistry to correct for common analytical interferences such as hematocrit.

### Dynamic Electrochemistry

Dynamic Electrochemistry involves making multiple measurements and re-adjusting the input stimulation signal in response to how the chemistry is progressing. This dynamic adjustment results in a much richer output signal that forms the basis for a “fingerprint” that the meter’s algorithms can analyze to develop correction factors to minimize the distortion caused by the

interfering factors, such as temperature, sample irregularity, hematocrit effect, test strip condition and abnormal test strip use.

## Reagent Composition

The One Drop test strip contains the enzyme glucose oxidase (*Aspergillus Niger*) and the mediator hexaamineruthenium (III) chloride.

## Calibration Traceability

The One Drop | Chrome Blood Glucose Monitoring System is plasma calibrated. These meters are factory calibrated and further calibration by the user is not necessary for operation. The calibration is traceable to NIST (D-glucose) SRM 917c.

## References

1. **Clinical and Laboratory Standards Institute.** *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition.* 2005. CLSI EP7-A2 (ISBN 1-56238-584-4).