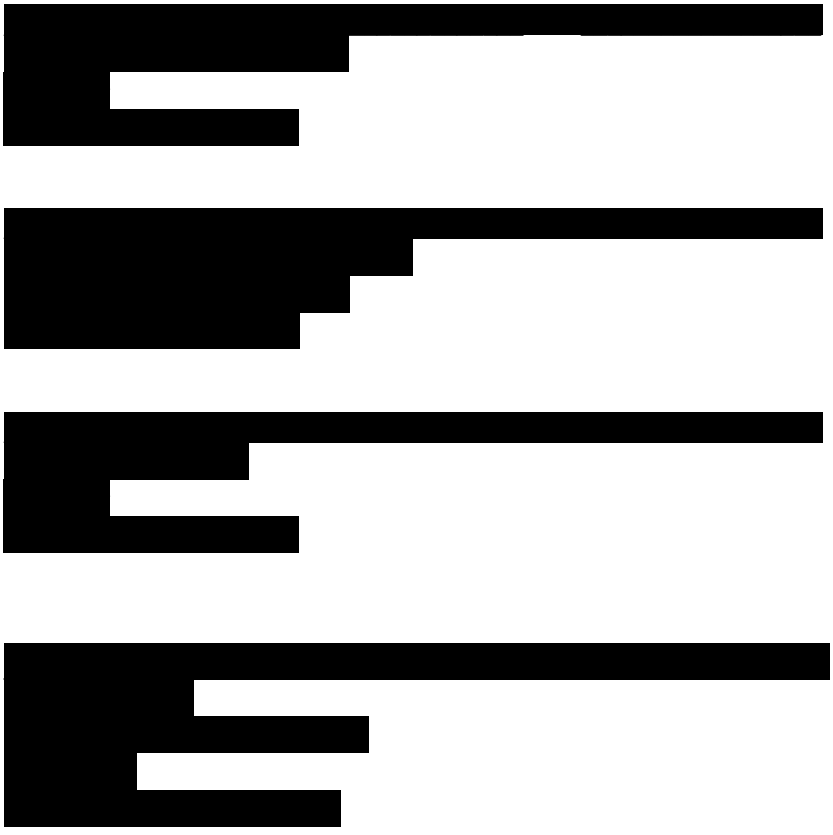
Statistical Analysis Plan: GCA-SAP-2019-001-01 for T-PLUS Trial

Ascensia Diabetes Care

Global Clinical Affairs

Reference Protocol:	GCA-PRO-2019-001-01
Protocol Title:	User Performance of the T-PLUS Blood Glucose Monitoring Systems



The statistical plan is intended to satisfy requirements for clinical study data analyses in:

FDA (2018) Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, Draft Guidance for Industry and Food and Drug Administration Staff, Issued 30Nov2018,

ISO 15197:2013 In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, 2nd Ed. 2023-05-15 (section 8)

ABBREVIATIONS

Abbreviation	Interpretation
Adj. R^2	Adjusted R Squared
BG	Blood Glucose
CAP	Capillary
Cum.	Cumulative
DM	Diabetes Management
Eval	Evaluable
GCA	Global Clinical Affairs
GE	Greater Than or Equal To
HbA1c	Hemoglobin A1c
HCT	Hematocrit
ISO	International Standards Organization
LCL	Lower Confidence Limit
LL	Lower Limit
Lower CI	Lower Confidence Limit
LT	Less Than
Max	Maximum
Min	Minimum
N	Sample Size
NA	Not Applicable or No Answer
PRO	Protocol
PWD	Person with Diabetes
RH	Relative Humidity
SD, Std Dev	Standard Deviation
SE, Std Err, Std Error	Standard Error
STAFF	Site Staff
SUB	Subject
Sy.x	Root Mean Square Error
Temp	Temperature

1. Sample Size

1.1 *ISO 15197:2013 Objective – Accuracy in People with Diabetes*

Let MeterBG = meter blood glucose result;

LabBG = laboratory method (YSI) comparator blood glucose result.

D = MeterBG – LabBG

RD = 100*(MeterBG – LabBG) / LabBG

Assume 315 evaluable results from people with diabetes. The ISO 15197:2013 acceptance criterion is that 95% of those evaluable results must satisfy the accuracy criteria:

$|D| = |\text{MeterBG} - \text{LabBG}| \leq 15$ mg/dL, for LabBG < 100 mg/dL

or

$|RD| = 100*|\text{MeterBG} - \text{LabBG}| / \text{LabBG} \leq 15\%$, for LabBG ≥ 100 mg/dL.

With n = 315, Xc = 300 results would be required to satisfy the accuracy criteria. At P_0 = 96.79%, there is approximately a 95% chance of satisfying the ISO objective. Conversely, at P_a = 92.77%, there is approximately a 95% chance of failing to satisfy the ISO objective.

1.2 *FDA Objective – Accuracy with All Subjects Included*

For the FDA accuracy objective, a result (MeterBG) is considered accurate if:

$|RD| = 100*|\text{MeterBG} - \text{LabBG}| / \text{LabBG} \leq 15\%$, regardless of the value of LabBG.

Assuming n = 350 evaluable results, Xc = 333 results would be required to satisfy the accuracy criteria. At P_0 = 96.65%, there is approximately a 95% chance of satisfying the FDA 15% objective. Conversely, at P_a = 92.81%, there is approximately a 95% chance of failing to satisfy the FDA accuracy objective.

The FDA guidance has a second criterion, that 99% of n evaluable results must have $|RD| \leq 20\%$. Inasmuch as the two criteria are considered separately, there is no consideration for multiplicity. For the n = 350, the 20% criterion requires a critical value of Xc = .99*350

= 346.5 → 347. For this critical value and sample size, with P_0 = 99.61%, there is approximately a 95% chance of satisfying the FDA 20% criterion. Conversely, there is approximately a 95% chance of failing to satisfy the 20% criterion if the chance of obtaining a result within ±20% of corresponding comparator measurement is only 97.8%.

Note that each glucose result obtained with the evaluation device will be considered either 'accurate' or 'not accurate', where accuracy depends on the particular test criterion.

1.3 Internal Objective

For subjects with diabetes only (PWDs):

The criterion is defined to be:

|D| ≤ 12.5 mg/dL if LabBG < 100mg/dL, or:

|RD| ≤ 12.5% if LabBG ≥ 100mg/dL

The hypothesis:

$$H_0: \Pr\{criterion\ met\} < 95\%$$

will be tested against the alternative:

$$H_1: \Pr\{criterion\ met\} \geq 95\%$$

With n = 315, the critical value is *Xc* = 294 yields a power to reject H0 if Pr{criterion met} = 0.95 is ~92.63%.

Table 1.1 summarizes the power statements made in 1.1, 1.2, and 1.3.

Table 1.1 Power Statements for ISO and FDA Acceptance Criteria

Criterion	N	Xc	Po*	Pr{PASS|Po}	Pa**	Pr{FAIL|Pa}
ISO	315	300	96.79%	95.02%	92.77%	94.95%
±12.5	315	294	95.00%	92.63%	90.60%	94.64%
FDA-15%	350	333	96.65%	95.00%	92.81%	94.95%
FDA-20%	350	347	99.61%	95.05%	97.80%	95.00%
*Po is the minimum required (hypothetical) probability that any measurement would meet the definition of an "accurate" result, in order to have approximately a 95% chance that at least Xc out of N results would be "accurate" (PASS)						
**Pa is the maximum required (hypothetical) probability that any measurement would meet the definition of an "accurate" result, in order to have approximately a 95% chance that fewer than Xc out of N results would be "accurate" (FAIL)						

In general, critical values depend on actual sample size. The sample size and associated critical values for accuracy tests (the minimum required numbers of "accurate" results) are determined by regulatory guidance. The values of Po and Pa are affected by actual sample size.

2. Blood Glucose Measurements

Some data analysis follows analyses and presentations described in ISO Section 15197:2013, Section 8. See Table 3 for scheme of data analysis, including capillary blood and venous blood.

Other data analysis follows analyses and presentations described in the FDA 2018 OTC Guidance. See Table 4 for scheme of FDA 2018 OTC data analysis, including capillary blood and venous blood.

Blood glucose measurements will all be made in units of mg/dL. Graphs (other than error grids) involving blood glucose concentrations will be constructed in both mg/dL and mmol/L (for ISO analyses; analyses for FDA reporting will include tables and graphs in mg/dL only). The conversion of *X mg/dL* to *Y mmol/L* will be as follows:

$$Ymmol\ /L = \frac{Xmg/dL}{18.016}$$

Linear regression will be performed on data comparisons as shown in Tables 6.1 and 6.2.

Modified Bland-Altman Plots – Modified Bland-Altman plots (difference between evaluation device results and reference results plotted against reference results) will be constructed for all comparisons described in Tables 6.1 and 6.2.

3. Accuracy Analyses

3.1 *ISO Objective*

At least 95% of the glucose results obtained using the evaluation device must be accurate, namely:

$$-15\% \le RD \le +15\% \qquad LabBG \ge 100 mg/dL$$

OR

$$-15 mg/dL \le D \le +15 mg/dL \qquad LabBG < 100 mg/dL$$

As discussed in section 0 (Sample Size), with n =315, the critical number (minimum) of accurate results is 300, which yields approximately a 95% chance of satisfying the ISO objective criterion if the actual probability that any result will be accurate is at least 96.79%. Symbolically, the ISO criterion is equivalent to testing the hypothesis:

$$H_0 : \text{Prob}\{accurate\} < 96.79\%$$

versus the alternative:

$$H_1 : \text{Prob}\{accurate\} \ge 96.79\%$$

There is approximately a 95% chance that the null will NOT be rejected if the actual probability that a result with the evaluation device would satisfy this definition of accuracy is only about 92.76%.

3.2 *Venous Goal*

Venous glucose results will be analyzed in the same fashion as the ISO accuracy objective for subject-generated capillary (fingerstick) results for only evaluable results from subjects with diabetes, and the same acceptance criteria applied.

3.3 FDA Objectives

3.3.1 95% within ±15%

With n = 350, at least *Xc* = 333 measurements must be within ±15% of LabBG. This requirement is equivalent to testing the hypothesis:

$$H_0: \Pr\{|RD| \leq 15\%\} < 0.9664$$

against the hypothesis:

$$H_1: \Pr\{|RD| \leq 15\%\} \geq 0.9664$$

with Pr{reject H_0|p=0.9664} ≈ 0.9488

3.3.2 99% within ±20%

With n = 350, at least Xc = 347 measurements must be within ±20% of LabBG. This requirement is equivalent to testing the hypothesis:

$$H_0: \Pr\{|RD| \leq 20\%\} < 0.9960$$

against the hypothesis:

$$H_1: \Pr\{|RD| \leq 20\%\} \geq 0.9960$$

with Pr{reject H_0|p=0.9960} ≈ 0.9466

3.4 Internal Accuracy Objective

The criterion is defined to be:

|D| ≤ 12.5 mg/dL if LabBG < 100mg/dL, or:

|RD| ≤ 12.5% if LabBG ≥ 100mg/dL

The hypothesis:

$$H_0: \Pr\{criterion\ met\} < 95\%$$

will be tested against the alternative:

$$H_1: \Pr\{criterion\ met\} \geq 95\%$$

With n = 350, the critical value is *Xc* = 327 yields a power to reject H0 if Pr{criterion met} = 0.95 is ~0.9246.

3.4.1 *Study-Staff-Generated Capillary Testing Goal*

Study-staff-generated capillary results will be analyzed in the same fashion as the ISO accuracy objective for subject-generated capillary (fingerstick) results for only evaluable results from subjects with diabetes, and the same acceptance criteria applied.

Study-staff-generated capillary results will be analyzed in the same fashion as the FDA accuracy objective for subject-generated capillary (fingerstick) results for only evaluable results from ALL subjects, and the same acceptance criteria applied.

3.5 *Some Additional Comments about Hypothesis Tests*

Power and risk calculations were made based on the assumption that n = 315 for the ISO accuracy objective, and for n = 350 for the FDA accuracy objective. It is possible that the total number of results may differ from the minimum requirement, depending on the numbers of subjects actually enrolled and the number of evaluable results. The critical value is always 95% of the total sample size of evaluable results. However, power statements made earlier were based on n = 315 or n = 350, so these statements may only be approximate.

No adjustment will be made for multiplicity. Each test will be evaluated without regard to the results of any other test.

3.6 *By-Site Analyses*

Only one site will be included in this study, so there will be no specific "by site" analyses.

3.7 *Descriptive Statistics on Differences (D) and Relative Differences (RD) from Reference*

Descriptive statistics: mean (average), standard deviation, median, minimum, and maximum of D (LabBG < 100 mg/dL) and RD (LabBG ≥ 100 mg/dL), will be computed.

3.8 *Confidence Intervals*

Confidence intervals (95%, two-sided) for all ISO and FDA objective proportions (percents) will be computed using the Clopper-Pearson[1] (1934) formula:

$$P_L = \frac{X * F^{-1}_{\alpha/2}(2X, 2(n-X+1))}{n-X+1+X * F^{-1}_{\alpha/2}(2X, 2(n-X+1))}$$

[1] Clopper, C.J., Pearson, E.S. (1934) The use of confidence or fiducial limits as illustrated in the case of the binomial, Biometrika, 26, 404-413

and:

$$P_U = \frac{X * F^{-1}_{1-\alpha/2}(2X, 2(n-X+1))}{n-X+1+X * F^{-1}_{1-\alpha/2}(2X, 2(n-X+1))}$$

P_L = lower limit

P_U = upper limit

X = number of "accurate" results (per the relevant definition of "accurate")

3.9 *Error Distributions*

The numbers and percents of values of D (LabBG < 100 mg/dL) falling within ±5, ±10, ±15, and ±20 mg/dL, and the numbers and percents of values of RD (LabBG ≥ 100 mg/dL) falling within ±5, ±10, ±15, and ±20 percent will be tabulated.

4. Regression, Modified Bland-Altman Plots, Radar Plot, and Outlier Analysis

4.1 *Weighted Least Squares (WLS)*

A linear regression of the meter results (MeterBG) against the YSI reference method results (LabBG) via weighted least squares (WLS) will be performed, with weights:

$$w = \frac{1}{YSI^2}$$

used to account for the proportional variance nature of blood glucose measurements (Draper and Smith, 1998)[2].

4.2 *Studentized Residuals and Outlier Identification*

Studentized residuals from the regression will be computed, i.e.,

[2] Draper, N. R., Smith, H., (1998) Applied Regression Analysis, 3rd Ed., John Wiley and Sons

$$e_i = y_i - \hat{y}_i$$

$$\varepsilon_i = \frac{e_i}{s_e\sqrt{1 - h_{ii}}}$$

That is, a studentized residual, ε, is the residual, e, divided by the standard error, $s_e\sqrt{1 - h_{ii}}$, of the residual. The variables h_{ii} are the diagonal elements of the "hat" matrix:

$$\boldsymbol{H} = \boldsymbol{X}[\boldsymbol{X}'\boldsymbol{W}^{-1}\boldsymbol{X}]^{-1}\boldsymbol{X}'\boldsymbol{W}^{-1}$$

The matrix $\boldsymbol{W}$ is a diagonal matrix with the regression weights, $w = \frac{1}{YSI^2}$ on the diagonal.

A meter result will be considered an "outlier" if its corresponding studentized residual is outside the interval $(\Phi^{-1}(0.005), \Phi^{-1}(0.995)) \approx$ (-2.576, +2.576), corresponding to a 99% interval for a standard normal variate. The function $\Phi^{-1}(p)$ is the inverse cumulative distribution function of a standard normal random variable; that is, the function is a z-score.

Confidence bands (99%) for the regression (individual) predictions will be computed. Scatter plots of MeterBG vs. LabBG will be constructed, with the regression line, the confidence bands, and the line of identity (Y = X) will all be plotted.

4.2 Modified Bland-Altman Plots

A Modified Bland-Altman Plot, with D plotted against LabBG (no limits on the range), will be constructed for subject-generated fingerstick, staff-generated fingerstick, and venous results. The limits for accuracy of individual results, per ISO:15197:2013, will also be plotted on the graphs.

4.3 Radar Plots

Radar plots will be made. Two plots (one with units of mg/dL and one with units of mmol/L) will be constructed using only PWD data (ISO), and will include ISO 15197:2013 bifurcation of criteria (difference for YSI < 100 mg/dL, relative difference when YSI ≥ 100 mg/dL). Another plot will be constructed for all evaluable data (FDA) in mg/dL.

5. Error Grid Analyses

Parkes consensus error grids will be constructed for combined strip lots, and combined sites as described in Tables 6.1 and 6.2. There is no criterion for percentage of values within the error grid zones.

6. Data Analysis Schemes

Table 6.1 -Data Analysis Scheme (per ISO15197:2013)

Blood Type	Data Comparison	Regression Tables	Bland Altman Plots	Accuracy	Error Grid	Error Interval tables (5,10,15, 20, >20%)
Capillary	Subject vs. YSI	x*	x***	x*	x*	x*
	Staff vs YSI	x*	x***	x*	x*	x*
Venous	Results vs. YSI	x*	x***	x*	x*	x*

* Combined sites

*** Plots with different symbols denoting whether observations are outliers

Table 6.2 -Data Analysis Scheme (per draft FDA OTC Guidance 2018)

Blood Type	Data Comparison	Regression Tables	Scatter Plots	Accuracy	Error Grid	Error Interval tables (5%,7%,10%,15%,20%)
Capillary	Subject vs. YSI	x*	x***	x*	x*	x*
	Staff vs YSI	x*	x***	x*	x*	x*

* Combined sites

*** Plots with different symbols denoting whether observations are outliers

Note – Samples outside +/- 20% will be identified and listed (per draft FDA 2018).

7. Subject Questionnaires

7.1 *Questionnaire 1 – Ease of Use*

Subject questionnaire 1 will consist in part of questions/statements for which a numerical score or rating (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree) will be provided by the subjects and entered by the study staff. For these numerically-scored questions, frequency distributions will be tabulated. For PWD subjects only (ISO 15197:2013 requirements), hypothesis tests for selected statements will be performed. The hypotheses are:

$$H_0: Pr\{response \geq 3\} < 90\% \text{ versus the alternative:}$$

$$H_a: Pr\{response \geq 3\} \geq 90\%$$

The critical number of responses greater than or equal to 3, Xc, is a function of the actual sample size, and will be chosen such that $0.95 = sup\ Pr\{X \geq X_c | 100p\% = 90\%\}$. For example, if n = 315, then Xc = 276, so that $Pr\{X \geq X_c | 100p\% = 90\%\} \approx 0.9299 \leq 0.95$. That is, 276 is the number of responses ≥ 3 which yields the largest value of $Pr\{X \geq X_c | 100p\% = 90\%\} \leq 0.95$ for n = 315.

7.2 *Questionnaire 2, Diabetes Management*

Frequencies of responses will be tabulated for statements/questions in the Diabetes Management Questionnaire.

8. Demographic, Diabetes History, Medications and Disease State Data

Descriptive statistics for subject Demographic, Diabetes History, Medications and Disease State data will be computed as appropriate. Histograms will be constructed where appropriate. A percentage of subjects < 65 years of age will be calculated.

9. Other Tables

9.1 Hematocrit Analysis

Hematocrit will be measured in singlet for each subject. For ISO 15197 analyses, subjects with a hematocrit determination that is out of range (outside the range 0-70%) cannot be used for blood glucose measurement comparisons.

The mean, median, minimum, maximum, and standard deviation, will be computed for hematocrit determinations.

9.2 Temperature and Humidity

Mean, median, standard deviation, minimum and maximum room temperature and humidity will be computed.

9.3 Glucose Distribution

The distribution of YSI glucose and a histogram (combined sites) for both capillary and venous blood will be provided. The mean, median, minimum, maximum, and standard deviation, will be computed for glucose distributions, by site and for both sites combined.

In addition, the number of capillary samples with concentrations <80 and > 250 mg/dL will be reported.

10. Data Listing

A listing of the data (excel sheet) is needed for the clinical study report. The listing should include: subject and staff fingerstick meter results, venous meter results, AST results, capillary and venous YSI results, subject ID, hematocrit.

11. Data Evaluability

Blood glucose data will be considered not evaluable for the following reasons:

- Subjects with either no hematocrit result or a hematocrit result outside of meter specifications (0-70%) (for FDA accuracy analyses, there is no requirement to have a hematocrit value; this requirement only pertains to ISO analyses).
- BG readings from **subject** meter tests that the subject feels were incorrectly completed. (If the subject states that the test s/he performed was completed incorrectly, and repeats the test, then the new BG reading will be used as the subject test.) Tests of each type (e.g., subject fingerstick) made be performed up to 3 times, i.e., repeated up to 2 times if the tester feels that the test was performed improperly.

- Failure to separate the plasma from the red cells (for YSI analysis) within 15 minutes of obtaining the corresponding evaluation meter result.
- Discrepant YSI replicate results will be excluded[†]. The comparator value for the subject will be the average of the non-outlier replicates. Should only a single replicate value be obtained for a given subject, it will be used as the comparator value.

- Subject plasma samples that do not have in-range serum controls tested after subject plasma test will be considered non evaluable.

Note: If supplemental or unplanned analyses are requested they will be presented in a supplemental report.

[†] Glucose values of the YSI replicates should be **within ±4 mg/dL when average of replicates < 100 or ±4%** of each other when average of replicates ≥ 100; if not, an additional assay should be run.

12. Laboratory Instrument Quality Control

Runs using serum control material at multiple levels will be executed daily for each laboratory glucose comparator instrument used in the study. The run means will be compared to lower and upper limits for each level. If the minimum and maximum value of individual measurements are within lower and upper limits, the run means do not need to be compared to those limits also.

A regression line will be fit using the instrument results regressed against target values as set by Ascensia Diabetes Care analytical laboratory. For levels with target values below 75 mg/dL, the within-run and between standard deviation (SD) will be computed; for levels with targets great than or equal to 75 mg/dL, the coefficient of variation (CV) will be computed, using the average over all runs.

Scatterplots of control result against targets, together with regression lines, for each instrument will be constructed. The Differences from target will be plotted against the target values for each instrument.

13. Meter Control Solution Results

Each meter unit used in the study will have control solution tests performed. The acceptable range of control solution results is specific to each meter, and the limits are provided by R&D or Quality Assurance. The control solution results must fall within prescribed limits in order for a meter to be used in the study. There are up to 3 attempts allowed to obtain a within-limit result for each meter.

Mock Tables and Graphs

Mock tables and graphs are intended to illustrate the general nature of such tables and graphs that are to be included in the study report. As such, they are facsimiles; actual tables and graphs may vary from the mock versions. For example, studies may have more than one site. The actual tables indicating results are computed by site would have results for each site included in the study.

Section 3 – Proportions: Applies to Sections 3.1-3.3, 3.5, 3.7

Table 3.1. Proportion -15 mg/dL ≤ D ≤ +15 mg/dL (LabBG < 100 mg/dL) or -15% ≤ RD ≤ +15% (LabBG ≥ 100 mg/dL)

Level	Count	Percent	Lower CI	Upper CI	1-Alpha
In	317	97.84%	95.61%	98.95%	0.95
Out	7	2.16%	1.05%	4.39%	0.95
Total	324				

Section 3 – Descriptive Statistics for D, RD

Table 3.2. Descriptive Statistics for D and RD

Level mg/dL	Variable	N	Mean	Std Dev	Min	Max	Median
LT 100	D (mg/dL)	74	2.19	4.470	-12.40	15.20	2.75
GE 100	RD (%)	297	3.17	4.945	-28.09	25.36	3.23
Level mmol/L	**Variable**	**N**	**Mean**	**Std Dev**	**Min**	**Max**	**Median**
LT 5.55	D (mg/dL)	74	0.12	0.25	-0.69	0.84	0.15
GE 5.55	RD (%)	297	3.17	4.945	-28.09	25.36	3.23

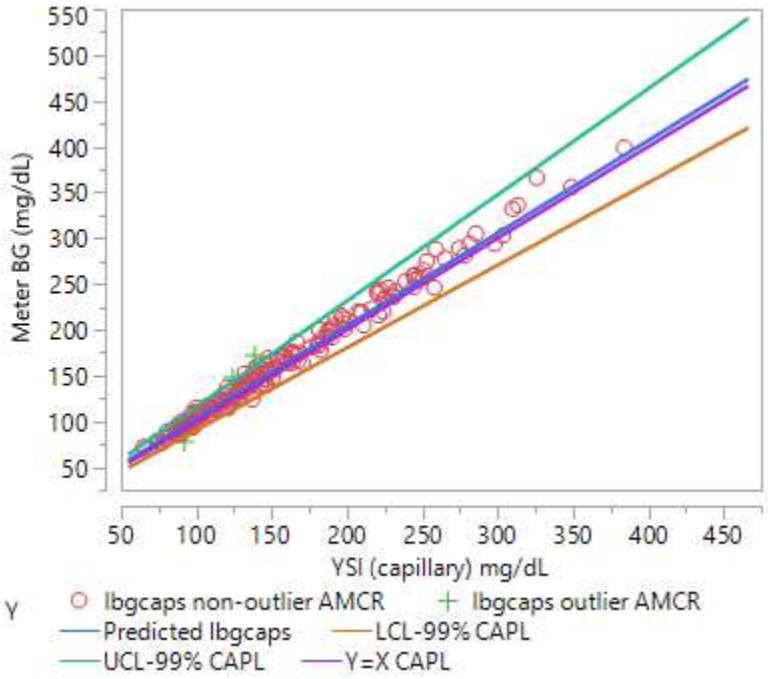
Section 4 – Regression Plot

Table 4.1 Regression Statistics

Variable	Term	Estimate	Std Error	LCL	UCL	Adj. R^2	RMSE	d.f.e.
Sub.Cap.	Intercept	1.253	0.9989	-0.712	3.218	0.9827	0.0481	322
	YSICAP	1.024	0.0076	1.009	1.039			322
AST	Intercept	0.834	1.3671	-1.856	3.524	0.9672	0.0663	323
	YSICAP	1.008	0.0103	0.988	1.029			323
Staff Test	Intercept	-0.776	0.8393	-2.427	0.875	0.9882	0.0405	322
	YSICAP	1.044	0.0063	1.032	1.057			322
Venous	Intercept	3.035	1.6399	-0.192	6.261	0.9506	0.0819	316
	YSIVEN	0.988	0.0127	0.963	1.013			316

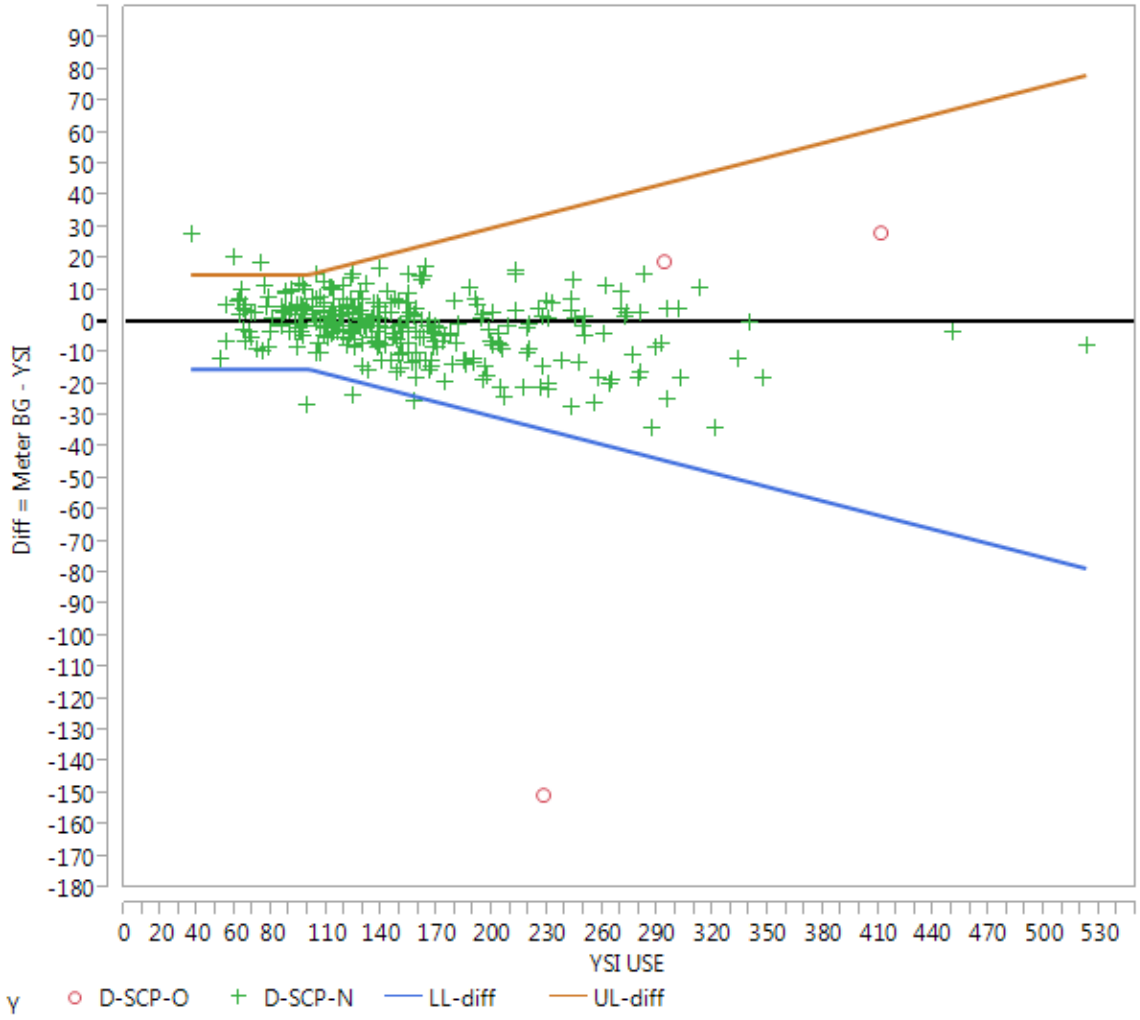
Estimate = Least Squares Value
Std Error = Standard Error of Estimate
LCL = Lower Confidence Limit
UCL = Upper Confidence Limit
Adj. R^2 = Adjusted R-squared
RMSE = Root Mean Square Error
d.f.e. = Degrees of Freedom for Error

Figure 4.1. Regression Plot



Section 4 – Modified Bland-Altman Plot

Figure 4.2. Modified Bland-Altman Plot



Note: D-SCP-O represents differences (D) for points identified as outliers; D-SCP-N are non-outlier points. LL-diff and UL-diff are the ISO 15197:2013, section 8 limits on accuracy.

Section 5 – Consensus (Parkes) Error Grid

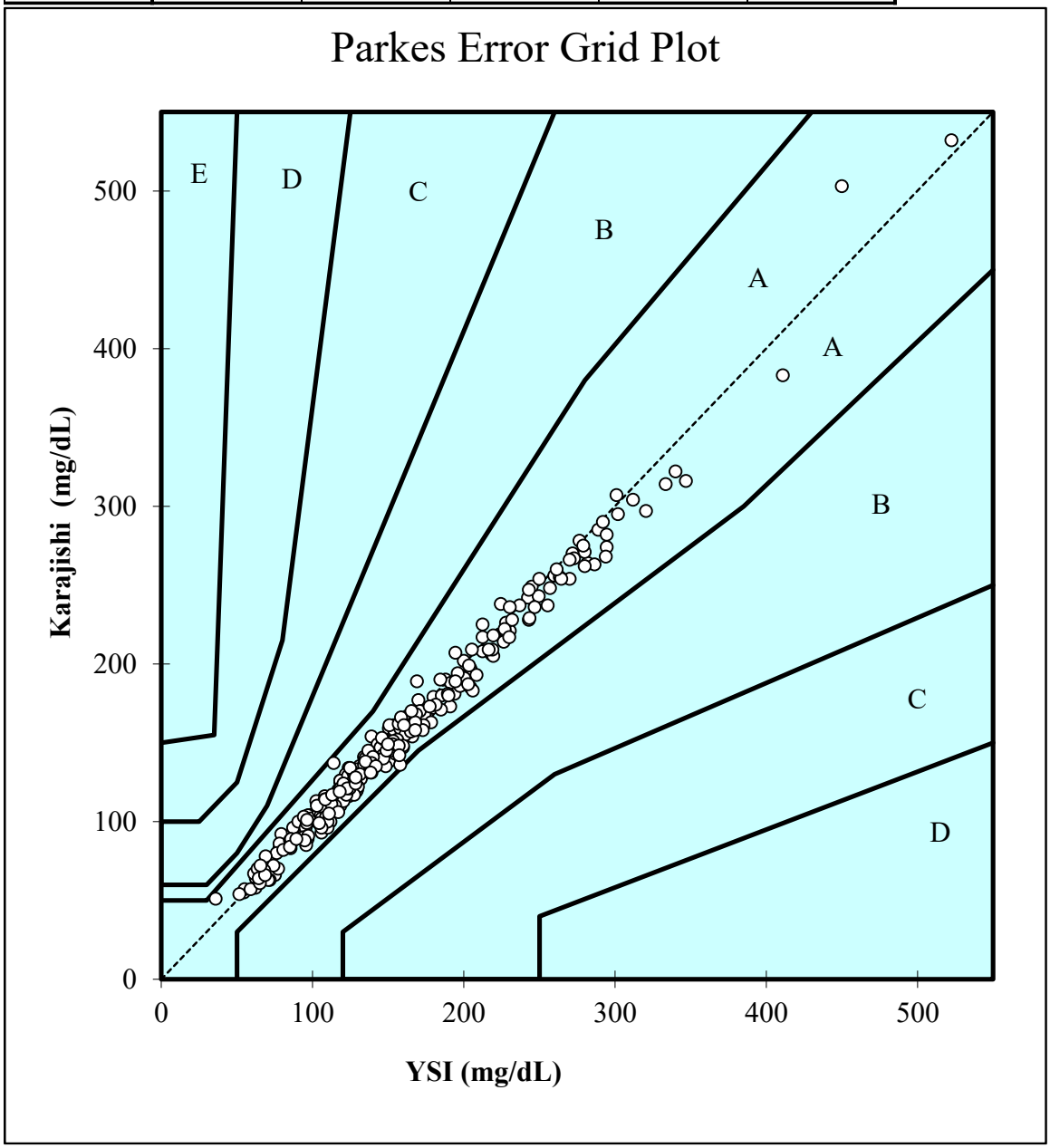
Figure 5.1. Parkes Error Grid

GCA-PRO-2014-002-01

Karajishi Contour(R) - Staff Capillary

Parkes Error Grid Analysis

Zone	A	B	C	D	E
Freq	326 out of 326	0 out of 326	0 out of 326	0 out of 326	0 out of 326
%Freq	100.0%	0.0%	0.0%	0.0%	0.0%



Section 7 – Subject Questionnaires

Table 7.1. Ease of Use Statements

Statement No.	Ease of Use
S1	I find it easy to do a fingerstick blood test with this meter.
S2	The meter display is easy to see and read.
S3	It was easy to understand my test results.
S4	I like the overall meter design.
S5	I find the meter easy to use.
S6	The instructions (User Guide and Quick Reference Guide) were easy to understand.
S7	The instructions clearly explain how to run a test.
S8	The instructions clearly explain what to do if an error message is displayed by the meter.

Table 7.2. Ease of Use Results
Note: columns labeled % ≥ Neutral and Crit. % will not appear in the table for the FDA report.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total No. Answered	% ≥ Neutral	Crit. %
S1	1	3	19	98	251	372	98.92%	87.63%
S2	1	0	1	76	294	372	99.73%	87.63%
S3	1	0	11	64	296	372	99.73%	87.63%
S4	2	2	39	125	204	372	98.92%	87.63%
S5	1	2	11	93	265	372	99.19%	87.63%
S6	2	2	31	105	232	372	98.92%	87.63%
S7	1	3	10	92	266	372	98.92%	87.63%
S8	1	0	17	98	256	372	99.73%	87.63%

Table 7.3. Diabetes Management Statements

	Diabetes Mgt. Survey (PWDs Only)
Statement No.	**Accuracy is important to help with:**
S1	1a) My ability to talk with my Health Care Professional
S2	1b) My satisfaction with my self-monitoring of diabetes.
S3	1c) My ability to manage my diabetes.
S4	1d) Preventing low blood sugars.
S5	1e) Understanding how food or exercise affects low blood sugars.
S6	1f) Using my results to gain better control of my diabetes.
S7	1g) Achieving greater peace of mind.
S8	**2. I prefer the meter that I just used to my regular meter**
	I use my current meter because:
S9	3a) My care provider gave it to me
S10	3b) My insurance company covers the strips
S11	3c) I think it is the most accurate meter

Table 7.4. Diabetes Management Results

			SCORE				
Statement	**0**	**1**	**2**	**3**	**4**	**5**	**Total***
Question 1	3	0	0	12	54	263	329
Question 2	2	0	1	4	64	261	330
Question 3	1	0	2	6	53	270	331
Question 4	9	0	1	9	63	250	323
Question 5	2	0	1	8	58	263	330
Question 6	0	0	2	1	48	281	332
Question 7	2	1	2	10	67	250	330
Question 8	16	12	13	95	75	121	316
Question 9	40	22	21	21	67	161	292
Question 10	26	28	16	18	55	189	306
Question 11	24	16	33	135	76	48	308
*Total number of subjects who responded							

Section 8all of these tables below are needed for ALL and only PWD

Table 8.1. Ethnicity

Ethnicity	Count	Percent
Hispanic or Latino	47	12.63%
Not Hispanic or Latino	320	86.02%
Not Reported	5	1.34%
Total	372	100.00%

Table 8.2. Race

Race	Count	Percent
White	305	81.99%
Black	32	8.60%
Asian	23	6.18%
Native American	7	1.88%
Hawaiian/Pacific Islander	4	1.08%
Not Reported	7	1.88%

Table 8.3. Languages Spoken

Laguage Spoken	Count	Percent
English	363	97.58%
Spanish	10	2.69%
BUNGABA	1	0.27%
HINDI, PUNJABI	1	0.27%
KANNADA	1	0.27%
TAGALOG	2	0.54%
URDU	2	0.54%
VIETNAMESE	1	0.27%

Table 8.4. Education

Education	Count	Percent
Bachelors degree or more	110	29.57%
High school graduate or equivalent	66	17.74%
Less than high school	7	1.88%
Not reported	2	0.54%
Some college or Associate degree	187	50.27%
Total	372	100.00%

Table 8.5. Occupation

Occupation	Count	Percent
Administrative	109	29.30%
Manufacturing	43	11.56%
Professional	113	30.38%
Sales/Services	122	32.80%
Student	74	19.89%
Retired	96	25.81%
Health Care Field	53	14.25%
Work at home	51	13.71%
Other	42	11.29%
Not reported	2	0.54%

Table 8.6. Gender

Gender	Count	Percent
Female	201	54.03%
Male	171	45.97%
Total	372	100.00%

Table 8.7. Age Statistics

N	Mean	SD	Median	Min	Max	# < 65	% < 65
376	52.1	15.60	55	18	81	295	78.46%

Table 8.8. Diabetes Type

Type	Count	Percent
Do not have diabetes	43	11.56%
Don't know (Type 1 or Type 2)	3	0.81%
Type 1	121	32.53%
Type 2	205	55.11%
Total	372	100.00%

Table 8.9. Diabetes History (PWD Subjects Only)

Variable	Level	Count	Percent
Time	1 to 3 months	6	1.82%
Since	4 to 6 months	1	0.30%
Diagnosis	7 to 12 months	3	0.91%
	13 months to 2 years	22	6.69%
	3 to 5 years	25	7.60%
	6 to 10 years	58	17.63%
	More than 10 years	214	65.05%
	Total	329	100.00%
Testing	1 time per day	54	16.41%
Frequency	2 times per day	63	19.15%
	3 times per day	49	14.89%
	4 times per day	35	10.64%
	I don't test my blood glucose	11	3.34%
	Less than 1 time per day	39	11.85%
	More than 4 times per day	78	23.71%
	Total	329	100.00%
Recommended	1 time per day	57	17.33%
Testing	2 times per day	55	16.72%
Frequency	3 times per day	61	18.54%
	4 times per day	52	15.81%
	Less than 1 time per day	10	3.04%
	More than 4 times per day	81	24.62%
	My HCP does not recommend BG testing	13	3.95%
	Total	329	100.00%
Insulin	Insulin pump	75	35.21%
Use	One or two injections per day	57	26.76%
Frequency	Three or more injections per day	81	38.03%
	Total	213	100.00%

Table 8.9. Diabetes History Continued (PWD Subjects Only)

Variable	Level	Count	Percent
HbA1c	6.0 % or lower	23	6.99%
	6.1 to 6.5 %	37	11.25%
	6.6 to 7.0 %	48	14.59%
	7.1 to 7.5 %	63	19.15%
	7.6 to 8.0 %	32	9.73%
	8.1 to 8.5 %	25	7.60%
	8.6 to 9.0 %	8	2.43%
	9.1 to 9.5 %	17	5.17%
	9.6 to 10.0 %	7	2.13%
	10.1 to 10.5 %	2	0.61%
	Greater than 10.5 %	14	4.26%
	I don't know	52	15.81%
	I have never gotten an A1C test	1	0.30%
	Total	329	100.00%
Type of HCP	Diabetologist	1	0.30%
	Endocrinologist	149	45.29%
	General/ Family practitioner	159	48.33%
	Internist	12	3.65%
	Other	8	2.43%
	Total	329	100.00%
Other HCP	ARNP	1	12.50%
	COMMUNITY CLINIC	1	12.50%
	D.0	1	12.50%
	INTERNAL MEDICINE	1	12.50%
	NURSE PRACTITIONER	2	25.00%
	P.A.	1	12.50%
	RN	1	12.50%
	Total	8	100.00%
Use	I do not know what DMS is	12	3.65%
Data Mgt.	No	259	78.72%
Software	No (do NOT use at home)	29	8.82%
	Yes	29	8.82%
	Total	329	100.00%
DM Software	Daily	2	6.90%
Frequency	Less than monthly	4	13.79%
of Use	Monthly	6	20.69%
	Only in preparation for Doctor's appointment	14	48.28%
	Weekly	3	10.35%
	Total	29	100.00%

Table 8.9. Diabetes History Continued (PWD Subjects Only)

Adjust Therapy	No	123	37.39%
based on	Yes	206	62.61%
BG Results?	Total	329	100.00%
Manage	No	116	35.26%
Diabetes with	Yes	213	64.74%
Insulin?	Total	329	100.00%

Table 8.10. Subjects Taking Pre-Defined List of Medications

Subject take any Drugs Listed?	Count	Percent
No	17	4.57%
Yes	355	95.43%
Total	372	100.00%

Table 8.11. Numbers and Percents of Subjects Taking Pre-Defined Medications

Abbreviation	Drug Name	Count	Percent
AMARYL	Amaryl / Glimepiride	7	1.88%
ASPIRIN	Aspirin	163	43.82%
COFFEE	Coffee / Caffeine	291	78.23%
EPHEDRIN	Ephedrine/ (Sudafed)	19	5.11%
GLUCOPHA	Glucophage / Metformin	159	42.74%
GLUCOTRO	Glucotrol / Glipizide	19	5.11%
MICRONAS	Micronase /Glyburide	7	1.88%
MOTRIN	Motrin/Ibuprofen	139	37.37%
PIOGLITA	Pioglitazone / Actos	4	1.08%
TETRACYC	Tetracycline	1	0.27%
TYLENOL	Tylenol / Acetaminophen	98	26.34%
VITAMINC	Vitamin C / Ascorbic Acid	93	25.00%
None	None	17	4.57%

Table 8.12. No. PWD Subjects with Pre-Defined Conditions

Condition:	No. PWD w/Condition	No. PWD	% PWD
Have any of following?	209	329	63.53%
Parkinson's	0	329	0.00%
Liver Disease	2	329	0.61%
Kidney Disease	14	329	4.26%
Hyperlipidemia	146	329	44.38%
Gout	16	329	4.86%
Hypertension	154	329	46.81%
Cardiac Disease	19	329	5.78%

Table 8.13. No. Non-PWD Subjects with Pre-Defined Conditions

Condition:	No. Non-PWD w/Condition	No. Non-PWD	% Non-PWD
Have any of following?	8	43	18.60%
Parkinson's	0	43	0.00%
Liver Disease	1	43	2.33%
Kidney Disease	0	43	0.00%
Hyperlipidemia	6	43	13.95%
Gout	0	43	0.00%
Hypertension	2	43	4.65%
Cardiac Disease	0	43	0.00%

Table 8.14. No. All Types of Subjects with Pre-Defined Conditions

Condition:	No. ANY w/Condition	No. Total	% Total
Have any of following?	217	372	58.33%
Parkinson's	0	372	0.00%
Liver Disease	3	372	0.81%
Kidney Disease	14	372	3.76%
Hyperlipidemia	152	372	40.86%
Gout	16	372	4.30%
Hypertension	156	372	41.94%
Cardiac Disease	19	372	5.11%

Section 9 – Other Tables – 9.1 and 9.3

Table 9.1. LabBG and HCT Descriptive Statistics

Variable	Population	Site	N	Mean	SD	Median	Min	Max	< 80	> 250
YSI CAP	PWD	1	163	152.80	65.214	139.50	44.95	455.50	11	14
YSI CAP	PWD	2	169	155.92	75.237	135.50	32.25	458.00	11	17
YSI CAP	PWD	Both	332	154.39	70.405	136.00	32.25	458.00	22	31
YSI CAP	ALL	1	184	146.23	64.330	126.75	44.95	455.50	11	14
YSI CAP	ALL	2	191	148.71	73.586	127.50	32.25	458.00	11	17
YSI CAP	ALL	Both	375	147.49	69.119	127.50	32.25	458.00	22	31
Hematocrit	PWD	1	163	43.09	4.036	43	34	59		
Hematocrit	PWD	2	169	43.44	3.767	44	33	52		
Hematocrit	PWD	Both	332	43.27	3.899	43	33	59		
Hematocrit	ALL	1	184	43.02	3.939	43	34	59		
Hematocrit	ALL	2	191	43.41	3.742	43	33	52		
Hematocrit	ALL	Both	375	43.22	3.840	43	33	59		
YSI VEN	PWD	1	162	149.18	65.075	136.50	47.30	455.00	15	12
YSI VEN	PWD	2	168	152.58	75.251	131.25	30.25	461.00	16	16
YSI VEN	PWD	Both	330	150.91	70.353	133.50	30.25	461.00	31	28

Note: HCT = hematocrit; YSI = capillary YSI LabBG; YSI-VEN = venous YSI LabBG

Section 9 – Temperature (Temp) and Relative Humidity (RH)

Table 9.2. Temperature and Relative Humidity

Site	Variable	N	Mean	SD	Median	Min	Max
1	Temperature (°F)	28	70.42	0.581	70.4	68.5	71.8
2	Temperature (°F)	44	72.08	0.965	72.3	70.0	74.7
1	Relative Humidity (%)	28	36.89	5.370	39.0	24.0	44.0
2	Relative Humidity (%)	44	37.34	4.467	37.0	27.0	47.0
Both	Temperature (°F)	72	71.43	1.164	71.5	68.5	74.7
Both	Relative Humidity (%)	72	37.17	4.806	38.0	24.0	47.0

Section 11 – Evaluability

Table 11.1. Numbers of Non-Evaluables

RESULT TYPE	Total No. Subjects	Non-eval	Missing Meter BG	No HCT	Usable N
SUBJECT RESULT	372	1	5	1	365
STUDY STAFF RESULT	372	1	1	1	369
Non-PWD-SUB	43	0	2	0	41
Non-PWD-STAFF	43	0	0	0	43
Total PWDs	329				
PWDs used for ISO-SUB CAP					324
PWDs used for ISO-STAFF CAP					326
VENOUS	329	0	10	1	318
Note: 3006 had missing venous BG as well as missing HCT					

Section 12 – Laboratory Instrument Quality Control

Table 12.1. Accuracy Statistics

					D = YSI - Target (mg/dL)				
Site	YSINUM	LEVEL	Target	N	Mean(D)	Std Dev(D)	Median(D)	Min(D)	Max(D)
1	10	2	50.0	38	-0.44	0.606	-0.40	-1.60	0.70
1	10	3	98.5	38	0.05	1.023	0.35	-1.90	1.50
1	10	4	197.3	38	-1.35	1.355	-1.30	-3.30	1.70
1	10	5	394.5	38	-1.87	3.560	-2.50	-8.50	4.50
1	11	2	50.0	38	-0.73	0.812	-0.70	-2.40	1.60
1	11	3	98.5	38	-0.50	1.400	-0.20	-3.40	1.50
1	11	4	197.3	38	-2.09	2.055	-1.80	-5.30	1.70
1	11	5	394.5	38	-3.79	3.631	-3.50	-15.50	2.50
2	48	2	50.0	34	-1.24	0.595	-1.30	-2.20	0.00
2	48	3	98.5	34	-1.52	1.402	-1.45	-4.30	1.00
2	48	4	197.3	34	-3.56	2.300	-3.80	-7.30	0.70
2	48	5	394.5	34	-3.82	3.169	-4.00	-9.50	4.50
2	98	2	50.0	34	-1.30	0.535	-1.20	-2.30	-0.20
2	98	3	98.5	34	-1.42	1.431	-1.35	-4.30	1.00
2	98	4	197.3	34	-4.01	1.915	-4.30	-8.30	-0.30
2	98	5	394.5	34	-3.94	3.067	-4.00	-10.50	1.50

					RD = 100(YSI - Target)/Target (%)				
Site	YSINUM	LEVEL	Target	N	Mean(RD)	Std Dev(RD)	Median(RD)	Min(RD)	Max(RD)
1	10	2	50.0	38	-0.88	1.212	-0.80	-3.20	1.40
1	10	3	98.5	38	0.05	1.039	0.36	-1.93	1.52
1	10	4	197.3	38	-0.69	0.687	-0.66	-1.67	0.86
1	10	5	394.5	38	-0.47	0.902	-0.63	-2.15	1.14
1	11	2	50.0	38	-1.47	1.624	-1.40	-4.80	3.20
1	11	3	98.5	38	-0.50	1.421	-0.20	-3.45	1.52
1	11	4	197.3	38	-1.06	1.042	-0.91	-2.69	0.86
1	11	5	394.5	38	-0.96	0.920	-0.89	-3.93	0.63
2	48	2	50.0	34	-2.48	1.190	-2.60	-4.40	0.00
2	48	3	98.5	34	-1.54	1.424	-1.47	-4.37	1.02
2	48	4	197.3	34	-1.81	1.166	-1.93	-3.70	0.35
2	48	5	394.5	34	-0.97	0.803	-1.01	-2.41	1.14
2	98	2	50.0	34	-2.60	1.070	-2.40	-4.60	-0.40
2	98	3	98.5	34	-1.44	1.452	-1.37	-4.37	1.02
2	98	4	197.3	34	-2.03	0.971	-2.18	-4.21	-0.15
2	98	5	394.5	34	-1.00	0.777	-1.01	-2.66	0.38

Table 12.2. Precision Statistics

LEVEL	YSINUM	Random Effect	Mean	SigEst	CV
2	10	Between	49.56	0.604	1.22%
2	10	Within	49.56	**0.111**	0.22%
2	10	Total	49.56	0.614	1.24%
3	10	Between	98.55	1.027	1.04%
3	10	Within	98.55	0.147	**0.15%**
3	10	Total	98.55	1.037	1.05%
4	10	Between	195.95	1.333	0.68%
4	10	Within	195.95	0.324	**0.17%**
4	10	Total	195.95	1.372	0.70%
5	10	Between	392.63	3.533	0.90%
5	10	Within	392.63	0.725	**0.18%**
5	10	Total	392.63	3.607	0.92%
2	11	Between	49.27	0.806	1.64%
2	11	Within	49.27	**0.165**	0.33%
2	11	Total	49.27	0.823	1.67%
3	11	Between	98.00	1.401	1.43%
3	11	Within	98.00	0.223	**0.23%**
3	11	Total	98.00	1.419	1.45%
4	11	Between	195.21	2.044	1.05%
4	11	Within	195.21	0.397	**0.20%**
4	11	Total	195.21	2.083	1.07%
5	11	Between	390.71	3.573	0.91%
5	11	Within	390.71	0.874	**0.22%**
5	11	Total	390.71	3.678	0.94%

Figure 12.1. Scatterplot with Regression Line

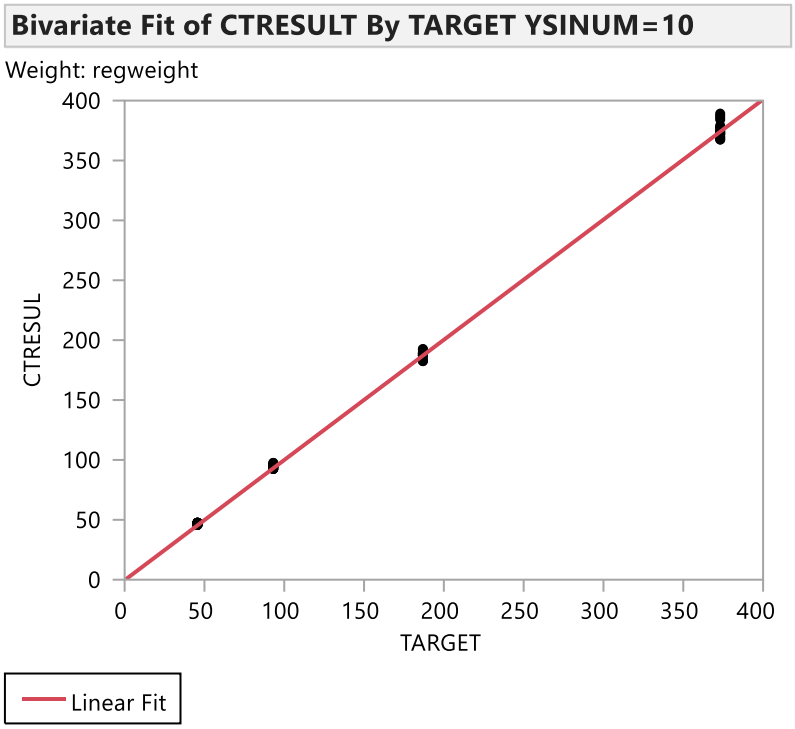
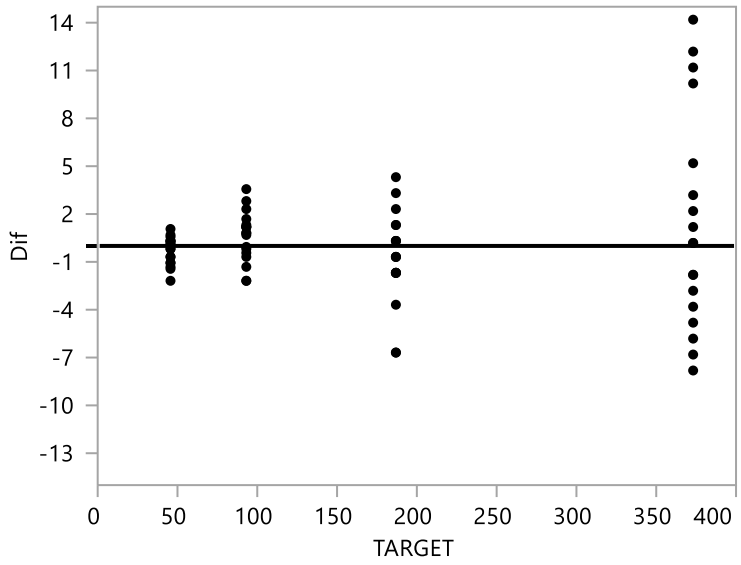


Figure 12.2. Difference from Target Plot (for YSI Control Solution Tests)



Diff = control result - target

Table 12.3. Regression Statistics

Site	Term	Estimate	Std Error	d.f.e.	LCL	UCL	Adj. R^2	Sy.x
1	Intercept	-0.212	0.1029	302	-0.415	-0.010	0.9996	0.0120
1	Slope	0.995	0.0012	302	0.992	0.997	0.9996	0.0120
2	Intercept	-0.710	0.1057	270	-0.918	-0.502	0.9996	0.0117
2	Slope	0.989	0.0012	270	0.987	0.992	0.9996	0.0117

Section 13 – Meter Controls

Table 13.1. Meter Control Results Summary

Site	Lot	N	Mean	SD	Median	Min	Max	LL	UL
1	BLUE	20	126.6	2.19	126.0	123	132	110	138
1	GREEN	20	128.0	2.31	128.0	124	131	110	137
1	RED	20	129.0	1.79	129.0	125	131	109	136
2	BLUE	20	121.2	2.07	121.0	117	125	110	138
2	GREEN	20	123.2	1.79	122.5	121	127	110	137
2	RED	20	121.7	1.72	122.0	118	125	109	136
LL = Lower Limit									
UL = Upper Limit									