A1CNow®+ System

Precision and Comparison Study Summary

1 PROTOCOL

This evaluation was conducted in June 2020. It consisted of precision testing and a comparative analysis of the A1CNow®+ system. The study compared fingerstick samples on the A1CNow+ system to venous whole blood samples tested on the NGSP Level II Laboratory Certified Tosoh G8 (Tosoh G8) at PTS Diagnostics, Sunnyvale, CA and on a Roche Cobas analyzer at a LabCorp reference laboratory (Roche Cobas). A total of twenty (20) subjects were tested.

At the test site, a PTS Diagnostics employee performed a venipuncture blood draw and collected one (1) EDTA whole blood lavender top tube and one (1) lithium heparin whole blood green top tube from each subject. An additional lithium heparin whole blood tube was drawn from three (3) subjects and retained in the testing area for use in the precision study. The lithium heparin tube from each subject was placed in a cooler with ice packs and shipped via overnight courier to PTS Diagnostics in Sunnyvale, CA for next day delivery for HbA1c analysis on the Tosoh G8. The EDTA tube from each subject was placed in a cooler with ice packs and transported to LabCorp for analysis on a Roche Cobas analyzer.

After the venipuncture, a PTS Diagnostics employee performed a fingerstick on each subject. A 5µL blood sample was collected for the A1CNow+ system using the blood collector provided in the kit and analyzed according to the instructions for use.

The precision study was performed using the whole blood collected in the lithium heparin tubes. Three samples, one each, with low, mid, and high values for HbA1c were run ten (10) times each on a single A1CNow+ system.

All samples tested for HbA1c were within the claimed measuring range of the analyzers used.

2 RESULTS

Evaluation by Average Difference

The following graphs and tables show the detailed analyses of the relationship of the results from the A1CNow+ System, the PTS Diagnostics Tosoh G8 and the LabCorp Roche Cobas analyzer.

The difference between the A1CNow+ result and the laboratory result is calculated pair-wise. The average of the differences is calculated.

The average differences (bias) were calculated from the individual paired % Bias results to the **Tosoh G8** analyzer (Table 2.1).
%Bias Roche to Tosoh = ((**Roche Cobas result** – Tosoh G8 Lab Result) ÷ Tosoh G8 Lab result) * 100
%Bias A1CNow+ to Tosoh= ((**A1CNow+ result** – Tosoh G8 Lab Result) ÷ Tosoh G8 Lab Result) * 100:
:

Table 2.1 Average % Bias vs. Tosoh G8

	Roche Cobas	A1CNow+ System
HbA1c (%)	-0.1%	-0.8%

The average difference (bias) was calculated from the individual paired % Bias to the **Roche Cobas** analyzer (Table 2.2).
%Bias A1CNow+ to Roche= ((A1CNow+ result – Roche Cobas result) ÷ Roche Cobas result) * 100:

Table 2.2 Average % Bias vs. Roche Cobas

	A1CNow+ System
HbA1c (%)	-0.7%

Analyte Summary

The summary of the linear regression and predicted bias data is shown in Section 3 for HbA1c in Tables 3.1-3.4. This data is then used to calculate the predicted bias at specific clinical decision values spanning the dynamic (measuring) range of the assay on the Tosoh G8. Actual predicted percent differences (bias) with the reference analyzers (Roche Cobas and Tosoh G8) are calculated as:

(A1CNow+ result – Reference method result) ÷ Reference method result * 100 = % Bias

3 HbA1c (%)

Table 3.1 HbA1c (%) vs. Tosoh G8

	Roche Cobas	A1CNow+ System
Number of Replicates (n)	20	20
Slope	1.00	0.97
y-Intercept	0.0	0.1
Correlation Coefficient (r)	0.996	0.960

Table 3.2 HbA1c (%) vs. Roche Cobas

vs. Roche Cobas	A1CNow+ System
Number of Replicates (n)	20
Slope	0.97
y-Intercept	0.2
Correlation Coefficient (r)	0.963

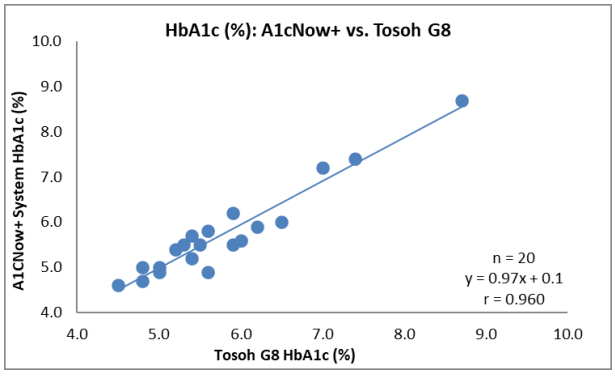
Table 3.3 HbA1c (%) Predicted Bias to Tosoh G8

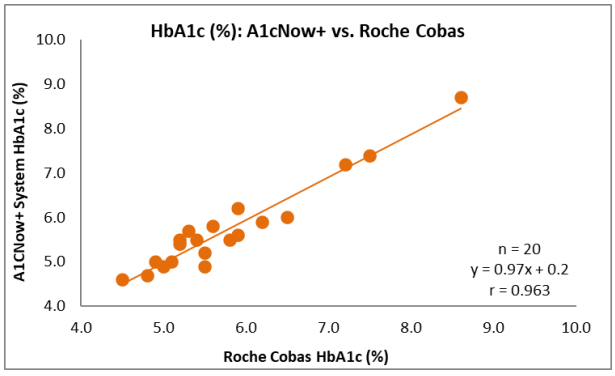
Tosoh G8	Roche Cobas	% Bias	A1CNow+ System	% Bias
4.0	4.0	-0.1%	4.0	0.3%
5.7	5.7	-0.1%	5.7	-0.8%
6.5	6.5	-0.1%	6.4	-1.1%
7.0	7.0	-0.1%	6.9	-1.3%
	Average % Bias	**-0.1%**		**-0.8%**

Table 3.4 HbA1c (%) Predicted Bias to Roche Cobas

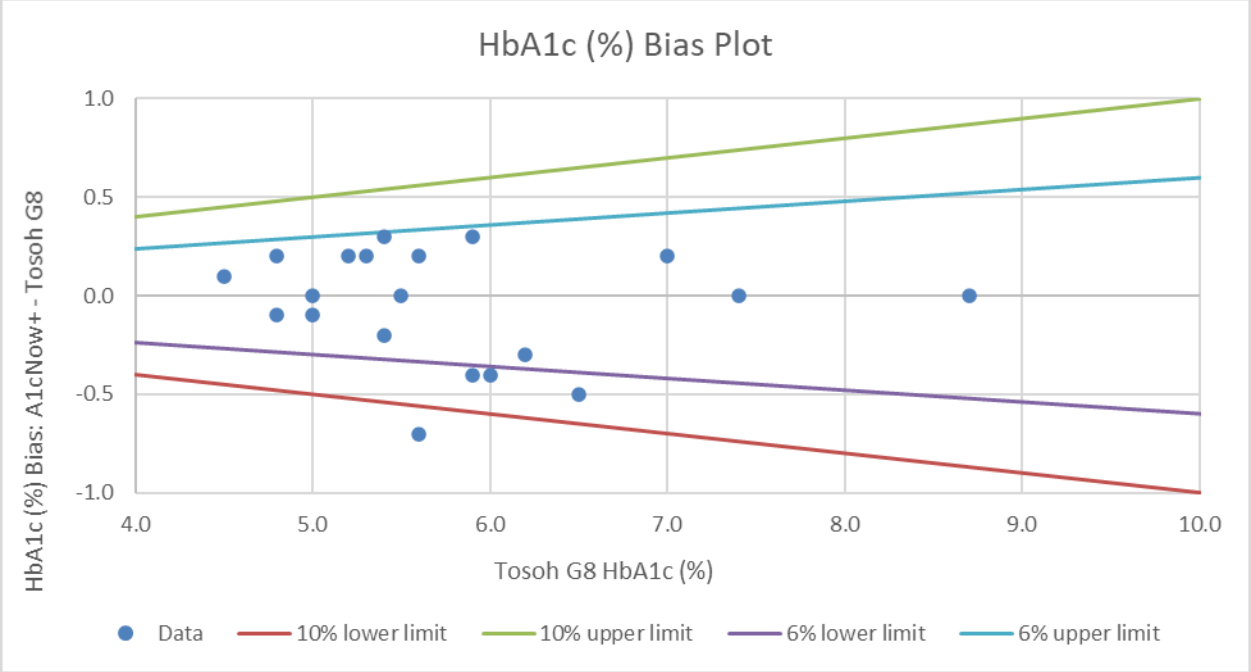
Roche Cobas	A1CNow+ System	% Bias
4.0	4.0	0.4%
5.7	5.7	-0.7%
6.5	6.4	-1.1%
7.0	6.9	-1.2%
	Average % Bias	**-0.7%**

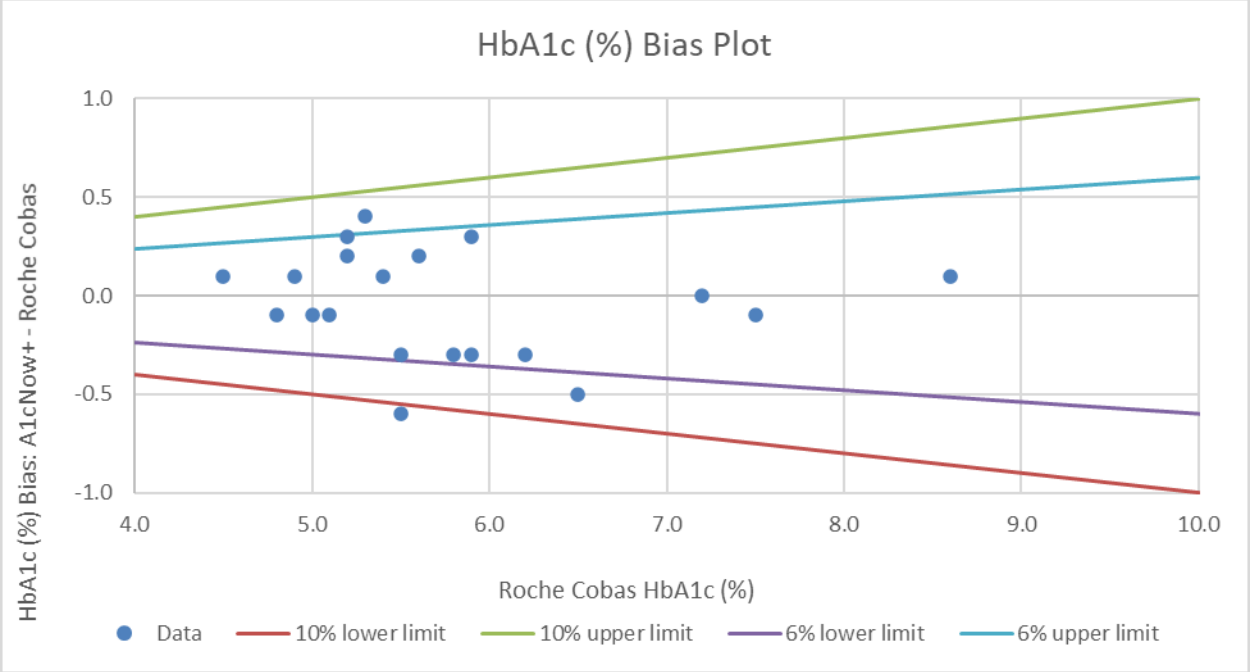
Predicted biases are calculated from the linear regression line of the data collected.





3 HbA1c (%), CONTINUED





4 RISK CLASSIFICATION

Each result was categorized based on traditional risk categories for HbA1c (Table 4.1). From these analyses, clinical agreement tables were compiled (Table 4.2 and Table 4.3) applying strict limits to quantify "Agreement." This means that a sample yielding a HbA1c (%) result of 5.6% for a reference system result of 5.7% was rated as a 1 category difference despite the clinical insignificance of the difference. These results are shown as the number of values where there is clinical agreement (Agree), a one category difference (1 Cat Diff) or a two-category difference (2 Cat Diff) between the A1CNow^{+} system and the reference laboratory result**.** In no instance was a "2 Category Difference" observed in this clinical evaluation for HbA1c.

Table 4.1 **Risk Classification (HbA1c)**

Categories	**HbA1c (%)**		
	<5.7	5.7 – 6.4	≥6.5

Table 4.2 Risk Classification Agreement Between Methods and Tosoh G8

	HbA1c (%)		
	Agree	**1 Cat Diff**	**2 Cat Diff**
Roche Cobas	20	0	0
A1CNow^{+} System	15	5	0

Table 4.3 Risk Classification Agreement Between Methods and Roche Cobas

	HbA1c (%)		
	Agree	**1 Cat Diff**	**2 Cat Diff**
A1CNow^{+} System	15	5	0

5 PRECISION

A1CNow+ System Results (HbA1c %)			
	Sample - Low	**Sample - Medium**	**Sample - High**
1	4.6	6.5	9.3
2	5.1	6.8	7.5
3	5.0	7.1	8.4
4	5.0	7.3	8.0
5	4.9	6.6	8.3
6	4.7	6.5	8.9
7	5.1	7.0	8.9
8	4.8	6.6	8.8
9	4.7	6.8	8.6
10	4.6	6.7	7.7
Number of replicates (n)	10	10	10
Average (HbA1c (%))	4.9	6.8	8.4
Standard Deviation (HbA1c (%))	0.2	0.3	0.6
CV (%)	4.0	4.0	6.8

6 OVERVIEW OF EVALUATION

PTS Diagnostics Technical Support

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Reference Methods: (X-axis)

PTS Diagnostics – Sunnyvale, CA: NGSP Level II Laboratory Certified Tosoh G8
LabCorp – Dublin, OH: Roche Cobas

Reagents Used: Accuracy and Precision

A1CNow+ System: Lot 2000228, Exp: 08/19/2021
A1CNow+ Controls: Lot 61050A, Exp: 11/30/2022

7 REGRESSION STATISTICS SUMMARY

Statistical Definitions

Slope: The slope of a line in the plane containing the *x* and *y* axes is generally represented by the letter *m*, and is defined as the change in the *y* coordinate divided by the corresponding change in the *x* coordinate, between two distinct points on the line. (A perfect slope is "1")

Intercept: Where a straight line crosses the Y-axis of a graph. (A perfect intercept is "0")

Correlation Coefficient (r Value): A statistic that gives a measure of how closely two variables are related, also known as the correlation coefficient. It represents the extent to which variations in one variable are related to variations in another or "goodness of fit."

Comparison Key Aspects

Any method comparison must be approached with a clear understanding of variables that affect the test results. The known variation of chemistry analytical systems must always be considered when evaluating observed bias. Such variation is not only evident between point-of-care testing and laboratory systems but also between laboratory systems. Even in the most closely aligned systems, two methods may "correlate" but rarely "match". Identity is not a prerequisite for acceptance, but rather an understanding of the bias at clinical decision limits for the analyte in question and the clinical consequences of these biases. The critical evaluation criterion is the placement of a given patient into appropriate risk categories by each system. In this analysis, a point-by-point comparison was made for each patient evaluating the risk classification category for each result.

Data Summary (PTS Diagnostics Internal Evaluation)

The A1CNow$^+$ test system in this study produced clinically comparable values for hemoglobin A1c compared to those reported for the same patient samples analyzed on the NGSP Level II Laboratory Certified Tosoh G8 (Tosoh G8) at PTS Diagnostics, Sunnyvale, CA and on a LabCorp Roche Cobas (Roche Cobas). The linear regression results between the methods indicate a good correlation between the A1CNow$^+$ analyzer point-of-care method and the reference laboratory methods for hemoglobin A1C. The risk classification tables demonstrate that the A1CNow$^+$ analyzer accurately identifies patient risk category with a high level of correlation with reference methods.

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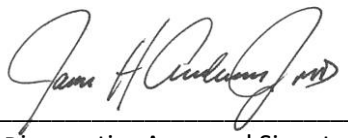
Medical Director



PTS Diagnostics Approval Signature

21 May 2021

Date