

1st Device

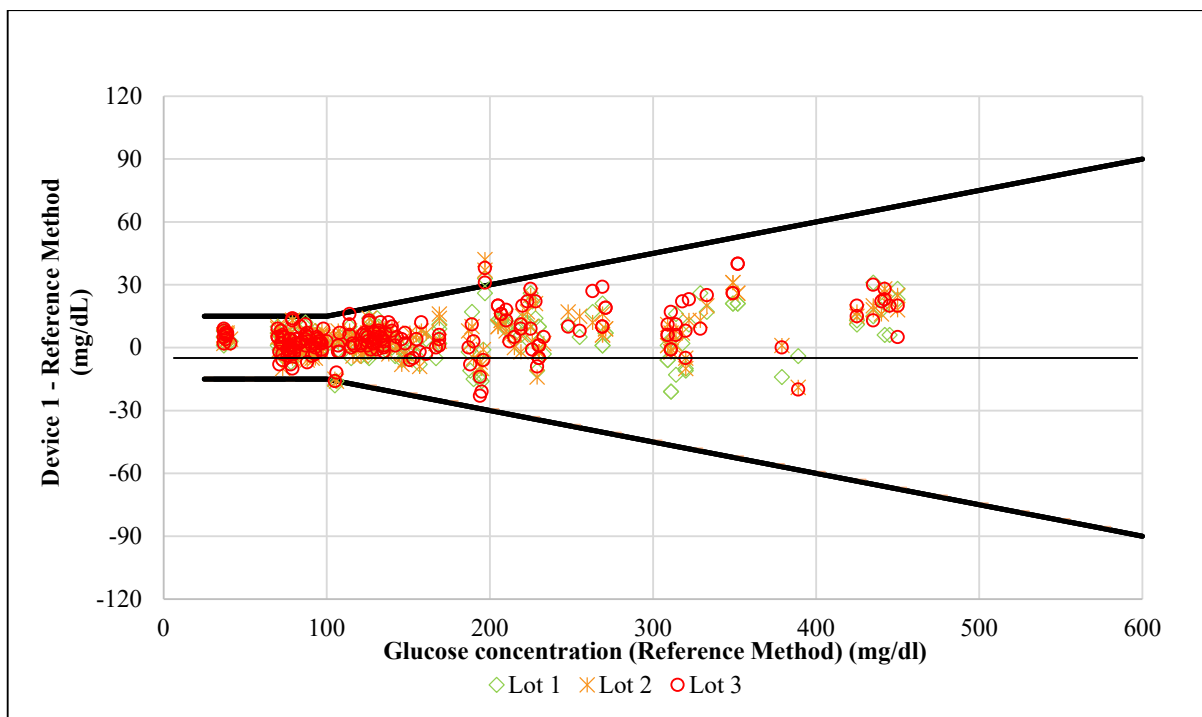


Figure S1 –Absolute differences between Device 1 and Reference Method

Bland-Altman – Device 1

Table S1 – Device 1 – Summary of bias analysis (Bland-Altman)

n = 200	Bias [mg/dl]	95% Limits of agreement [mg/dl]
Reagent system lot 1:	3.8 (95%CI: 2.57; 5.09)	-13.89 – 21.56
Reagent system lot 2:	4.9 (95%CI: 3.68; 6.18)	-12.67 – 22.53
Reagent system lot 3:	5.87 (95%CI: 4.46; 7.27)	-13.93 – 25.66

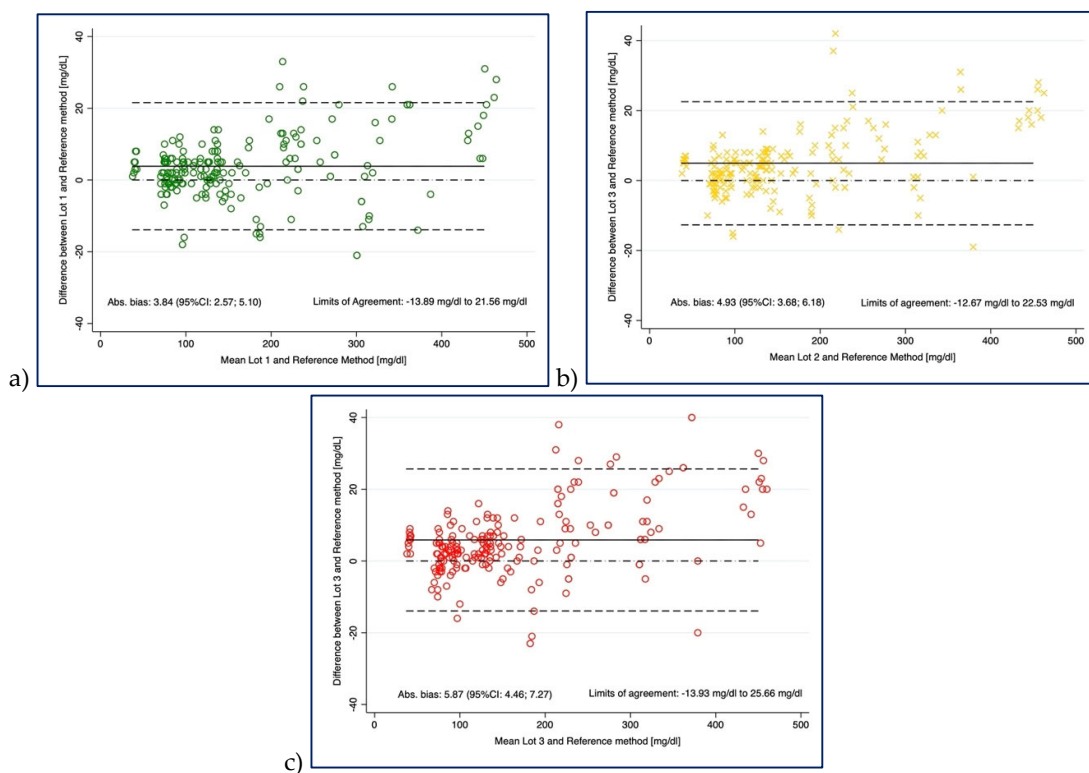


Figure S2 – Device 1 - Bland-Altman plot for a) Lot 1; b) Lot 2; c) Lot 3

Passing Bablok Regression – Device 1

Table S2 – Device 1 - Summary of regression analysis (Passing and Bablok)

n = 200	Regression
Reagent system lot 1:	$y = -0.21 + 1.03x$
Reagent system lot 2:	$y = -1.04 + 1.04x$
Reagent system lot 3:	$y = -1.61 + 1.04x$

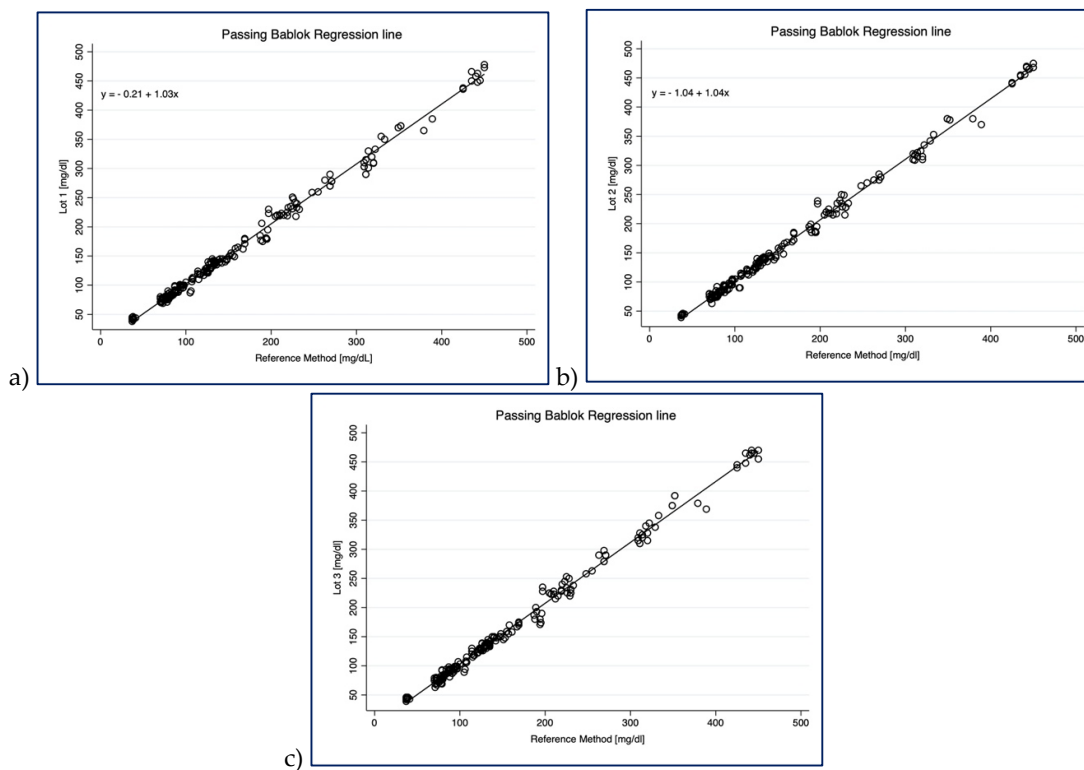


Figure S3 – Device 1 - Passing Bablok regression for a) Lot 1; b) Lot 2; c) Lot 3

System accuracy acceptability - Consensus Error Grid (CEG) – Device 1

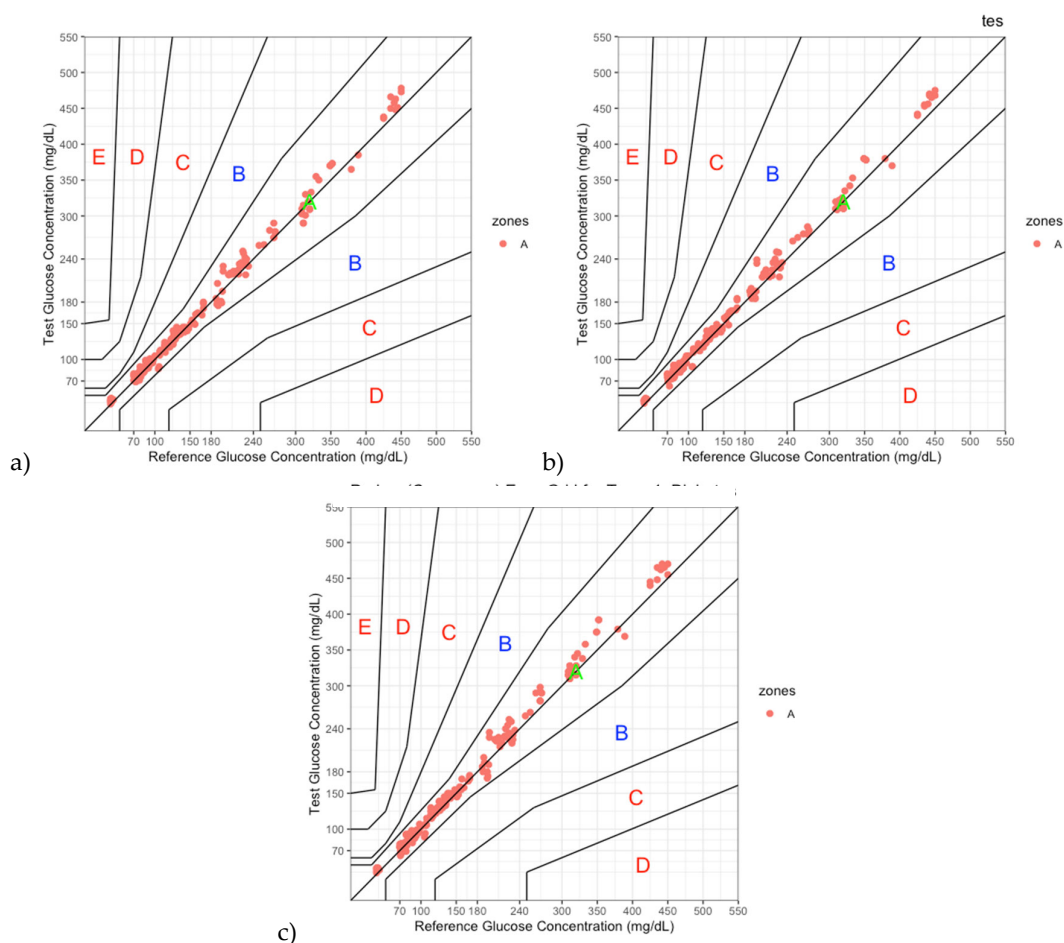


Figure S4 – Device 1 - Consensus Error Grid a) Lot 1; b) Lot 2; c) Lot 3 - For Lot 1, 200 values are in Zone A; for Lot 2, 199 values are in Zone A and one in Zone B; for Lot 3, 200 values are in Zone A. Therefore, 599 of 600 values (99.8%) are within Zones A and B.

2nd Device

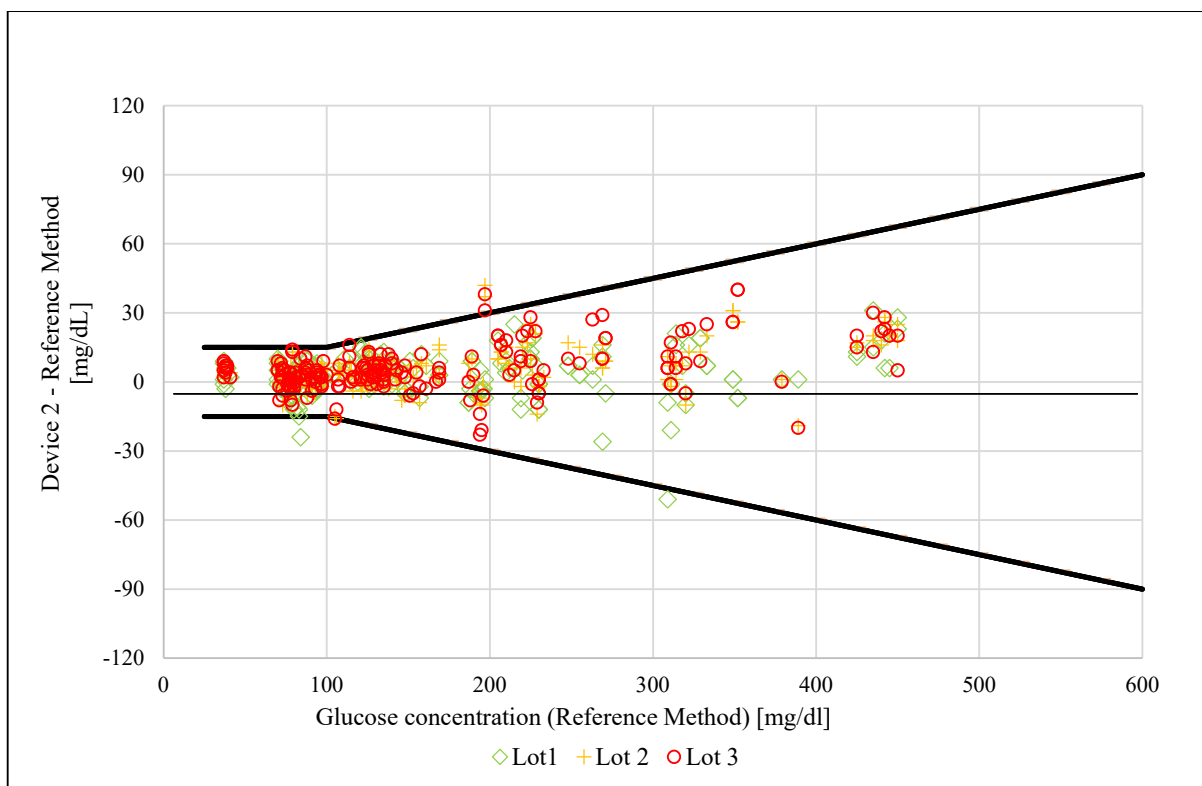


Figure S5 – Absolute differences between Device 2 and Reference Method

Bland-Altman – Device 2

Table S3 – Device 2 - Summary of bias analysis (Bland-Altman)

n = 200	Bias [mg/dl]	95% Limits of agreement [mg/dl]
Reagent system lot 1:	2.9	-15.27 – 21.11
Reagent system lot 2:	3.0	-14.86 – 20.76
Reagent system lot 3:	4.1	-13.62 – 21.83

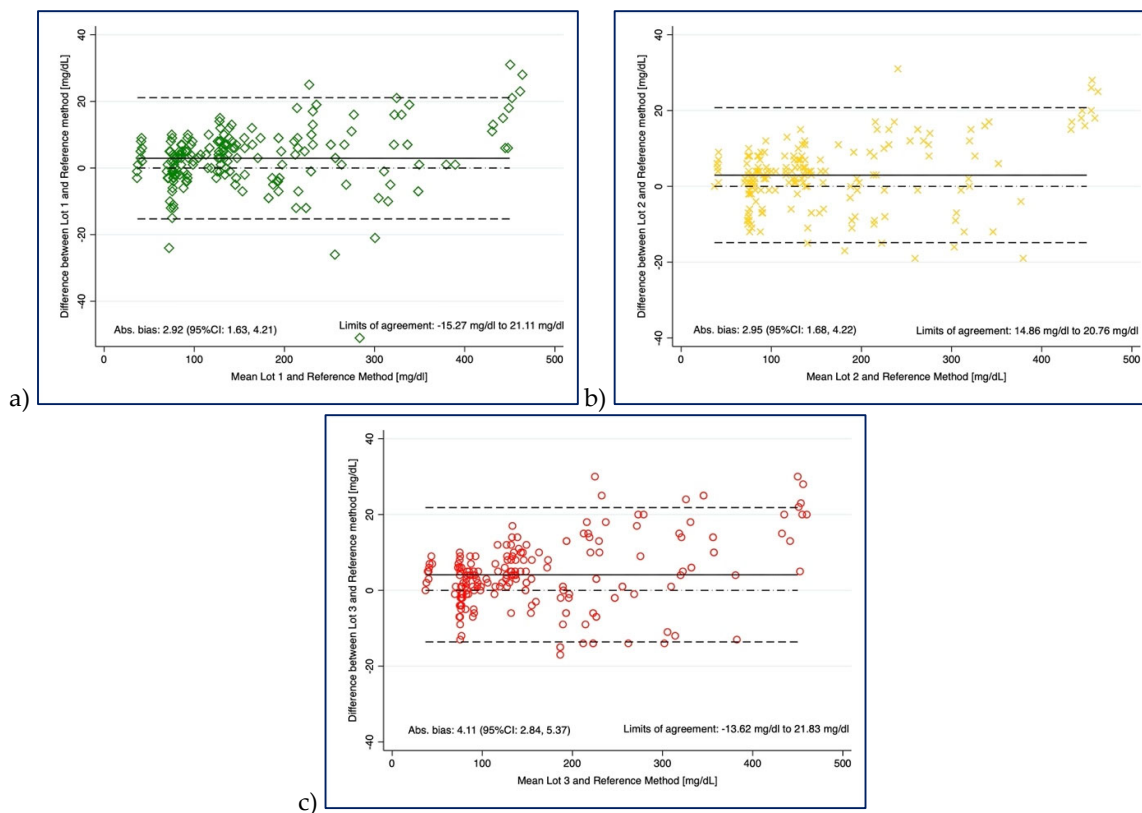


Figure S6 – Device 2 - Bland-Altman plot for a) Lot 1; b) Lot 2; c) Lot 3

Passing Bablok Regression – Device 2

Table S4 - Device 2 - Summary of regression analysis (Passing and Bablok)

n = 200	Regression
Reagent system lot 1:	$y = 0.17 + 1.03x$
Reagent system lot 2:	$y = -0.12 + 1.03x$
Reagent system lot 3:	$y = -0.44 + 1.03x$

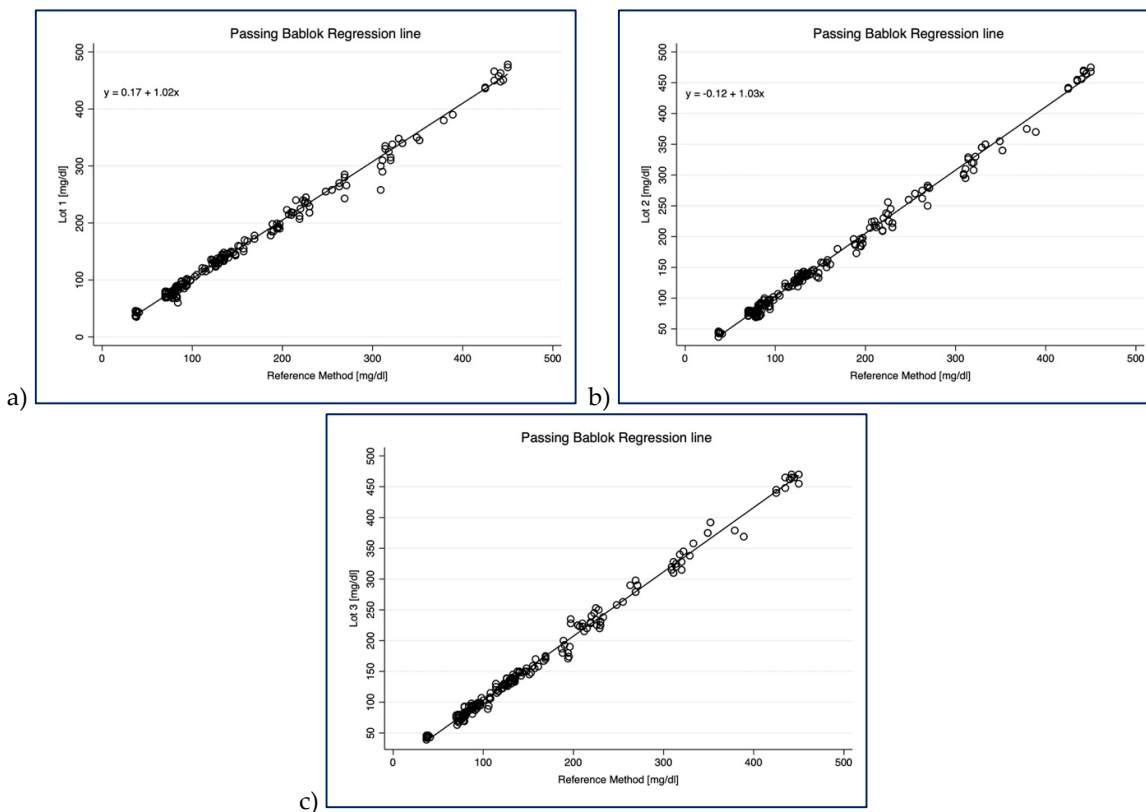


Figure S7 – Device 2 - Passing Bablok Regression for a) Lot 1; b) Lot 2; c) Lot 3.

System accuracy acceptability - Consensus Error Grid (CEG) – Device 2

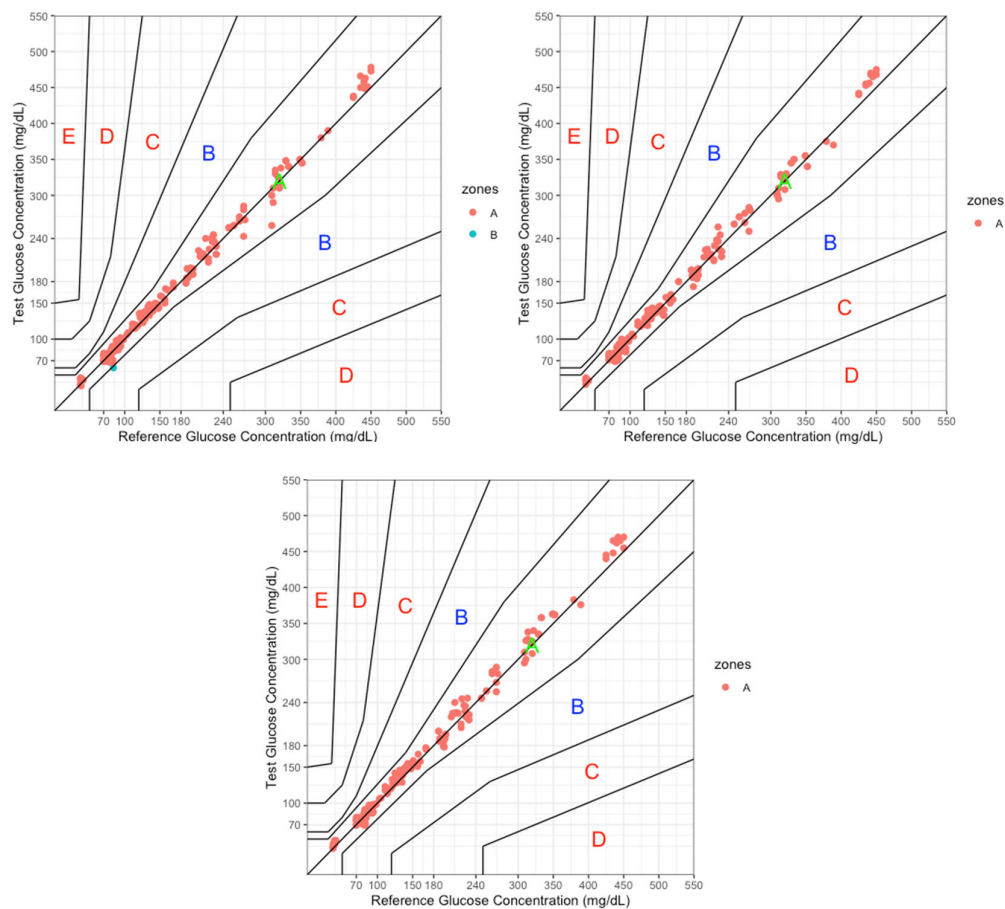


Figure S8 – Device 2 - Consensus Error Grid for a) Lot 1; b) Lot 2; c) Lot 3. For Lot 1, 198 values are in Zone A and two in Zone B; for Lot 2, 200 values are in Zone A; for Lot 3, 200 values are in Zone A. Therefore, 598 of 600 values (99.7%) are within Zones A and B.