Supplementary Material

Impact of glucose measuring systems and sample type on diagnosis rates of diabetes mellitus

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Supplementary Tables

Table S1 Compliance with CLSI indicators for glucose monitor studies adapted from Mahoney and Ellison [1].

CLSI (NCCLS) C30-A2 factors for glucose monitor evaluation studies	
Blood sample	**Our Study**
Blood sample type (e.g., venous, capillary) is appropriate for monitor method.	Yes
Blood hematocrit checked to be within monitor's acceptable range.	Yes
Appropriate anticoagulants, blood additives, or preservatives (if used).	Yes
Blood sample collection method	
Catheter is properly flushed of IV solution prior to sampling (if done).	Yes
Skin is cleaned and dried prior to puncture (if done).	Yes
Blood sample handling	
Monitor and reference method are both tested from the same sample.	Yes

Blood is tested (or centrifuged) within 5 min of monitor test. Centrifuged plasma is tested with reference method within 60 min of monitor test.	Yes
Operators are trained to manufacturer's instructions.	Yes
Monitor is tested in duplicate.	Yes (Only outpatient cohort)
Reference method	
Laboratory method checked for stability and for being within its QC control limits.	Yes
Laboratory method is tested in duplicate.	Yes (Only outpatient cohort)
Laboratory method is verified with NIST standard reference materials (optional).	Yes (German equivalent)
Laboratory duplicates are within 4% or 0.22 mmol/l (4 mg/dl) (or else excluded).	See figure 10
Statistics and Acceptibility Criteria	
Distribution of glucose in blood samples spans monitor's measurement range.	Yes
Specimen sample size is ≤ 40 specimen.	Yes
For glucose < 4.2 mmol/l (75 mg/dl), monitor result is accurate if within ± 0.83 mmol/L (15 mg/dL) of laboratory average.	See figure 10
For glucose > 4.2 mmol/l (75 mg/dl), monitor result is accurate if within ± 20% of laboratory average.	See figure 10
Individual monitor results are compared to the mean of duplicate results from laboratory analyzer.	See figure 10

Supplementary figures

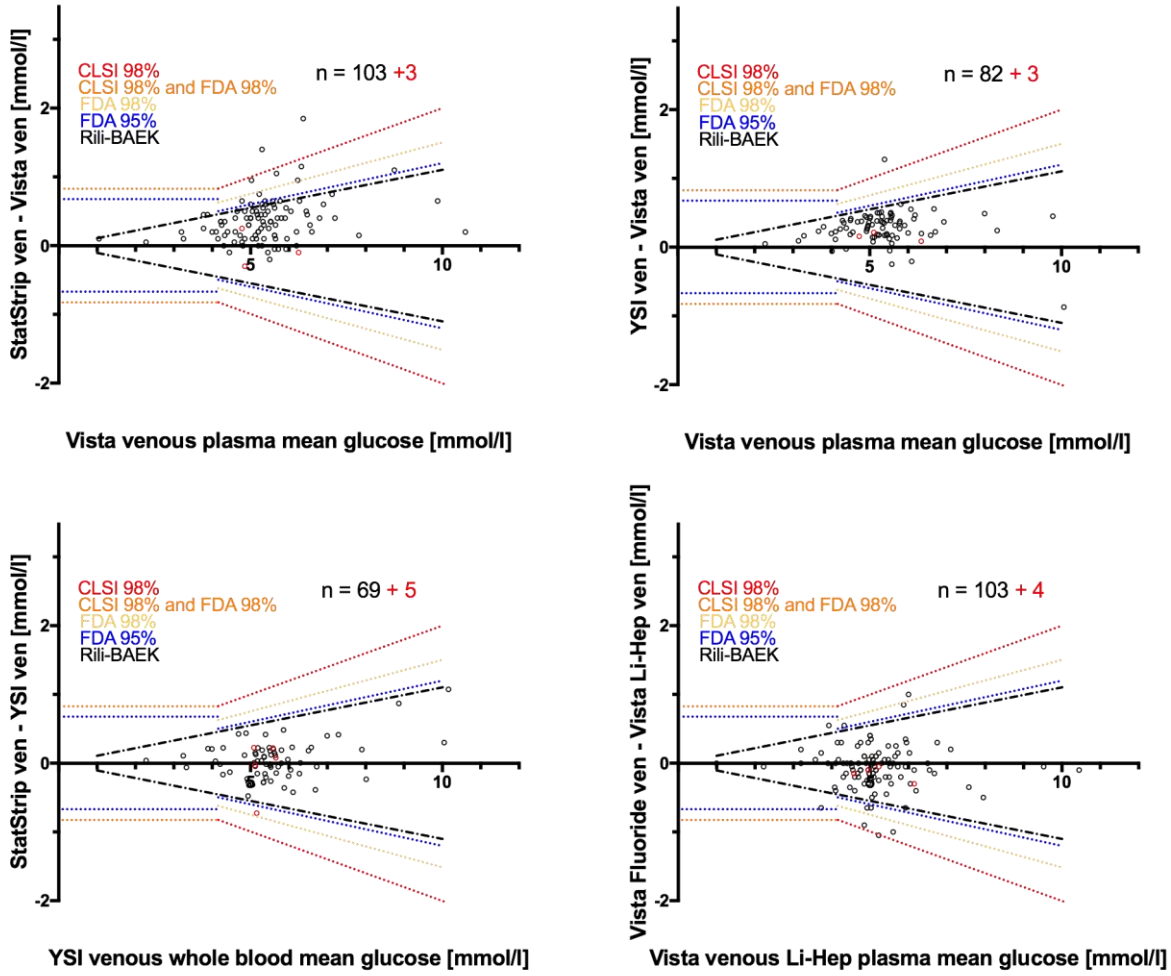

Figure S1. Bland-Altmann plots comparing outpatient venous POCT and fluoride samples to our core laboratory reference and comparison between venous measurements of the two POCT systems using CLSI C30-A2 criteria found in table 4. The number of measurements compared are shown and values excluded due to the CLSI requiring laboratory duplicates to be within 4% or 0.22 mmol/l are displayed in red.

References

1. Mahoney, J. and J. Ellison, *Assessing the quality of glucose monitor studies: a critical evaluation of published reports.* Clinical chemistry, 2007. **53**(6): p. 1122-8.