

## EVALUATION OF FOUR CAPILLARY GLUCOSE METERS

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### Background

New Zealand consumers with diabetes and their health professionals expect capillary glucose meter results to reflect a corresponding laboratory venous glucose value. Thus, although the true glucose concentration of a capillary sample tends to be higher than that of a corresponding venous sample, consumers expect their capillary glucose meter and strip system to be calibrated to read as a venous sample.

Capillary glucose meter results display more variability around the true result (ie have lower accuracy and precision) than does a laboratory venous sample. Several criteria have been proposed in regard to defining an acceptable level of accuracy and precision for meters. No meter on the market reaches the high standard of American Diabetes Association recommendations. More commonly used criteria are those of the National Committee on Clinical Laboratory Standards and the similar ISO15197 standard, which stipulates that <5% of readings should fall outside the limits of  $\pm 20\%$  from the reference value or  $\pm 0.83\text{mmol/L}$  if glucose is  $<4\text{mmol/L}$ .

Another method for assessing meter performance from a clinical perspective is Clarke error grid analysis. This was later refined by Parkes *et al*, who produced a Consensus Grid. Results displayed on these grids probably give the best intuitive understanding of meter performance from a clinical perspective. Results from all four meters studied are therefore given below as both Clarke and Consensus grid analyses.

Glucose meters should not display significant systematic bias. Systematic bias suggests problems with calibration.

### Methodology

The performance of four different makes of glucose meters (Freestyle, Care Sens II, Care Sens POP and On Call Plus) was assessed by comparing capillary results from two meters of each make (ie 8 capillary samples in total), with a simultaneously collected venous sample. Samples were collected from 50 diabetic outpatients, with either type 1 or type 2 diabetes and a haematocrit  $>0.30$ . For the purposes of this study, the capillary glucose result used in the analysis was the mean of the two results collected from each make of meter. The study had regional Ethics committee approval.

## Results

Results are displayed below in the Clarke and Consensus grid analyses. The venous sample ie reference value is displayed along the x axis. The corresponding mean capillary value is displayed along the y axis. The errors grids assign a specific level of clinical risk to any possible capillary glucose error as follows:

A - <20% deviation

B - deviation that leads to no change in treatments

C - overcorrection of an acceptable glucose level

D - dangerous failure to detect and treat abnormal glucose levels

E - erroneous treatment

All meters performed satisfactorily ie virtually all results fell within the A and B zones. The On Call Plus meter did however have 10% of results in the B zone and result in the D zone on the Clarke error grid. (Analysing results from each of the two On Call Plus meters separately produced similar grid results ie the errors were not confined to one meter). The On Call Plus meter also showed significant negative bias that was especially apparent at higher glucose values ie this meter tended to read capillary results around 10% lower than venous results. All meters performed to ISO 15197 standards.

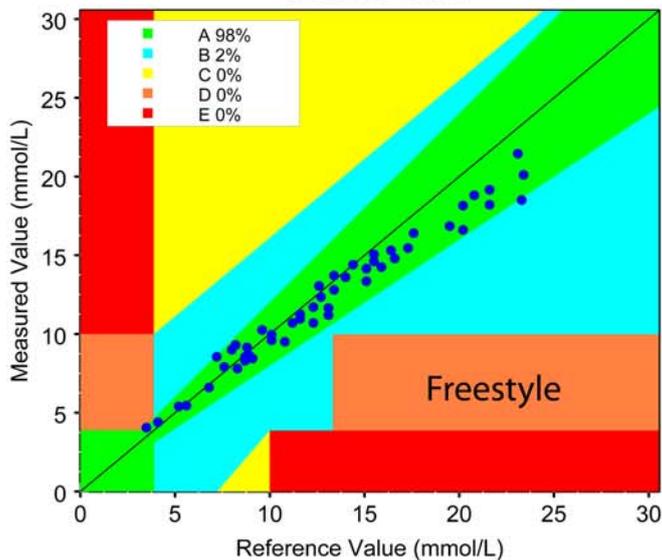
## Conclusions

Under controlled conditions, using trained observers, all four meters tested showed satisfactory performance. The On Call Plus meter did however display subtle differences in performance characteristics when compared to the Freestyle, Care Sens II and Care Sens POP meters. There are several limitations to interpretation of study results. Only 50 patients were tested and a larger sample size may have detected further subtle differences between meter performance. It was not ethically acceptable to test hypoglycaemic subjects, thus performance characteristics below a glucose value of 4mmol/L are unknown. Consumer testing of the meters was not undertaken, thus the study findings may not reflect the 'real world' setting. Despite these caveats, all four meters performed to a satisfactory level and their performance appears similar to that of the two meters currently on the New Zealand market, namely the Roche Performa and Precision Xceed.

X Method: venous

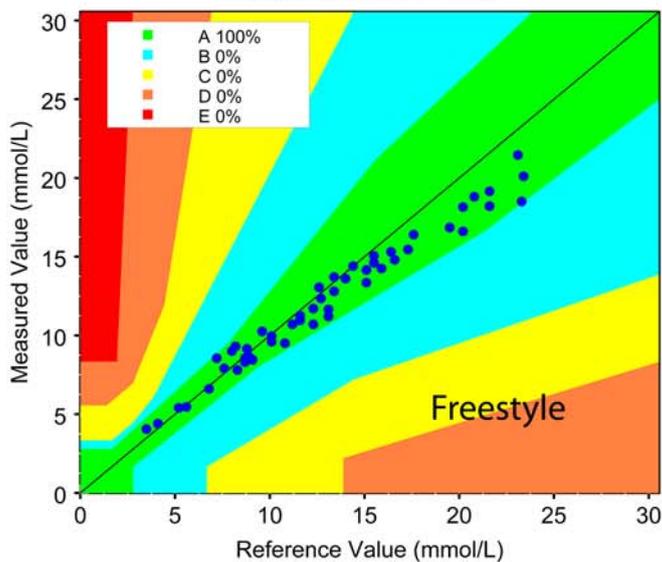
Y Method: capillary

Clarke Grid



Region	Count	Percent	Cum Percent
A	49	98%	98%
B	1	2%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	50		

Consensus Grid

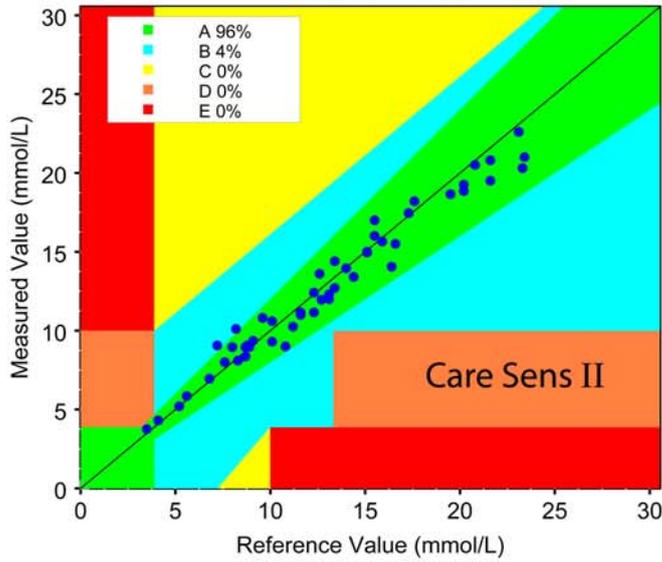


Region	Count	Percent	Cum Percent
A	50	100%	100%
B	0	0%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	50		

X Method: venous

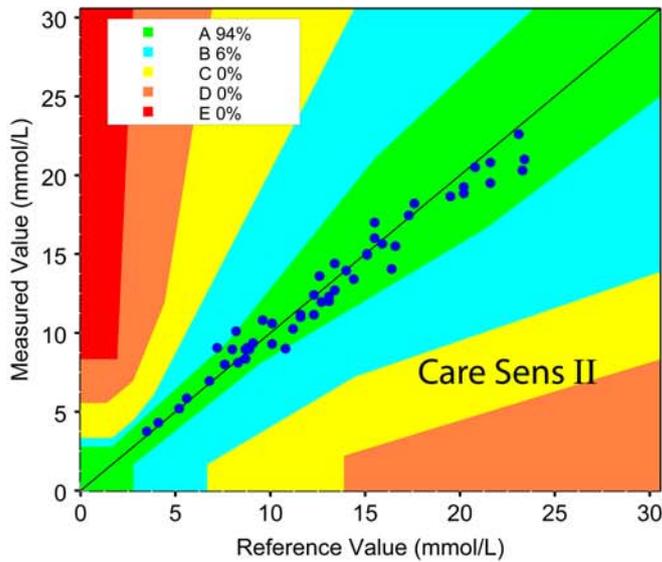
Y Method: capillary

Clarke Grid



Region	Count	Percent	Cum Percent
A	48	96%	96%
B	2	4%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	50		

Consensus Grid

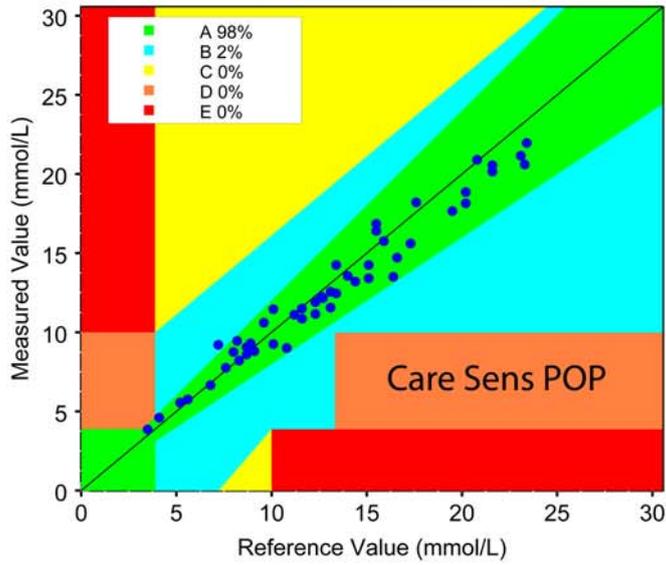


Region	Count	Percent	Cum Percent
A	47	94%	94%
B	3	6%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	50		

X Method: venous

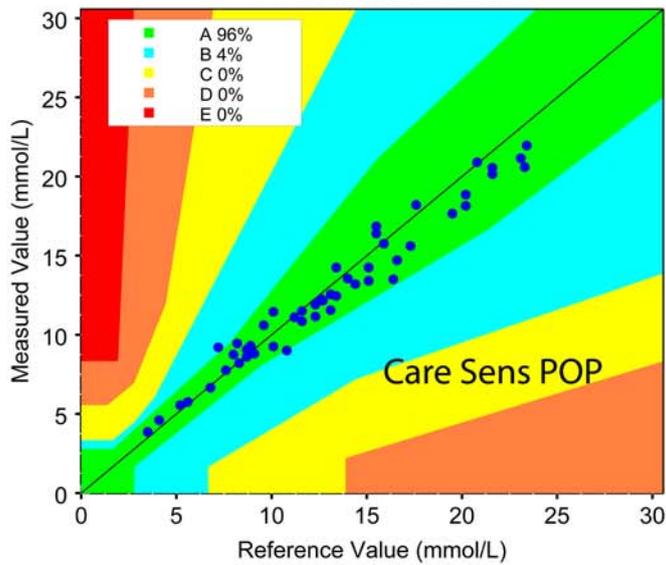
Y Method: capillary

Clarke Grid



Region	Count	Percent	Cum Percent
A	49	98%	98%
B	1	2%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	50		

Consensus Grid

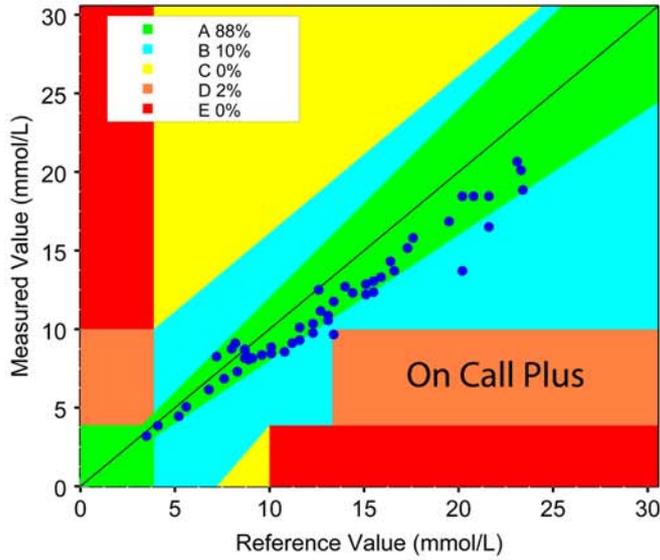


Region	Count	Percent	Cum Percent
A	48	96%	96%
B	2	4%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	50		

X Method: venous

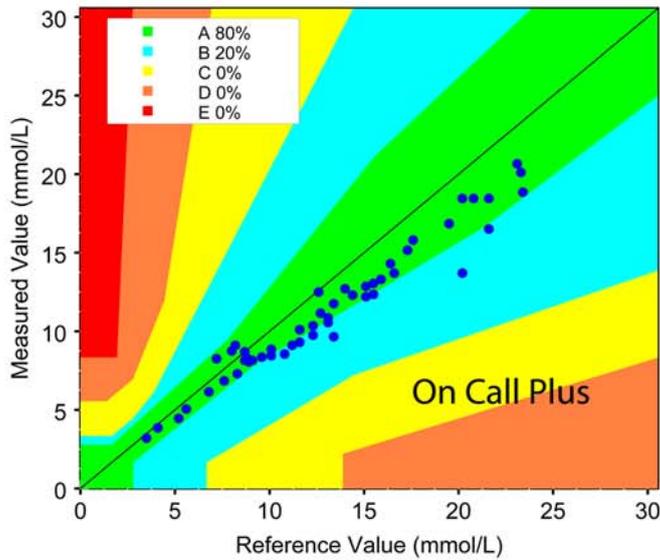
Y Method: capillary

Clarke Grid



Region	Count	Percent	Cum Percent
A	44	88%	88%
B	5	10%	98%
C	0	0%	98%
D	1	2%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	50		

Consensus Grid



Region	Count	Percent	Cum Percent
A	40	80%	80%
B	10	20%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	50		