

# Clinical Data for URiGHT PLUS One

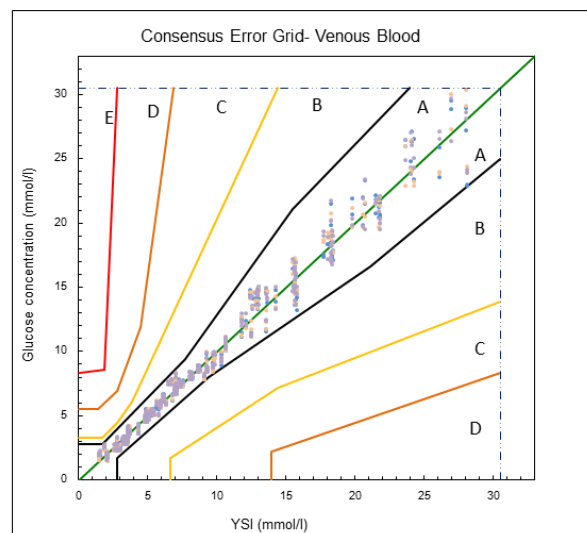
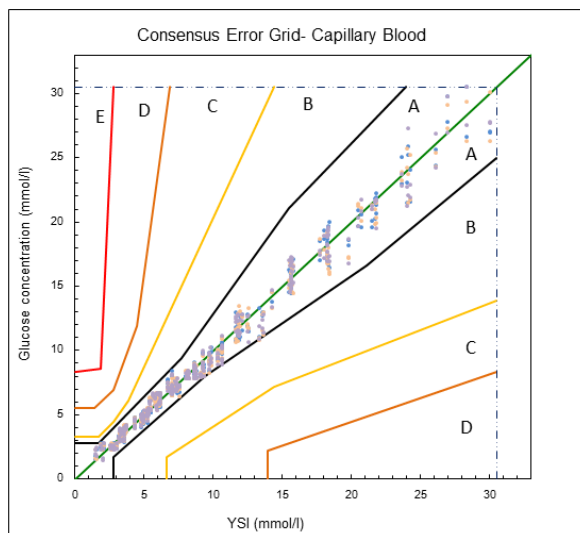
## Summary

- The clinical accuracy study followed the guideline of ISO 15197: 2013 and EN ISO 15197: 2015.
- Clinical data demonstrated PLUS One met the current accuracy standards of ISO 15197: 2013 and EN ISO 15197: 2015.
- Out of total 960 tests, average 98% (> 95%) fell in the range of  $\pm 15\text{mg/dL}$  or  $\pm 15\%$  ( $\pm 0.83\text{mmol/L}$  or  $\pm 15\%$ ) from the reference value.
- The study showed the accuracy performance of PLUS One monitoring system could be used on healthcare professionals and self-testing.

## Capillary & venous test results

- When the sample < 100mg/dL, 99% of the sample fell within  $\pm 15\text{mg/dL}$
- When the sample  $\geq 100\text{mg/dL}$ , 97% of the sample fell within  $\pm 15\%$

Test strip lot	n	$\pm 15\text{mg/dL}$ or $\pm 15\%$ ( $\pm 0.83\text{mmol/L}$ or $\pm 15\%$ )	n	Within $\pm 15\text{mg/dL}$ (Within $\pm 0.83\text{mmol/L}$ )	n	Within $\pm 15\%$
<b>Capillary blood testing</b>						
Total	960	942 (98.1%)	312	310 (99.4%)	648	632 (97.5%)
TD13B105-B0I	320	315 (98.4%)	104	103 (99.0%)	216	212 (98.1%)
TD13D215-B0E	320	313 (97.8%)	104	103 (99.0%)	216	210 (97.2%)
TD13E107-B0D	320	314 (98.1%)	104	104 (100%)	216	210 (97.2%)
<b>Venous blood testing</b>						
Total	960	940 (97.9%)	306	306 (100%)	654	634 (96.9%)
TD13B105-B0I	320	310 (96.9%)	102	102 (100%)	218	208 (95.4%)
TD13D215-B0E	320	315 (98.4%)	102	102 (100%)	218	213 (97.7%)
TD13E107-B0D	320	315 (98.4%)	102	102 (100%)	218	213 (97.7%)



Results of error grid analysis demonstrated that 100% of the results fall in zone A which indicates the meters are clinical accurate.