

# Clinical Data for URiGHT PLUS Mini

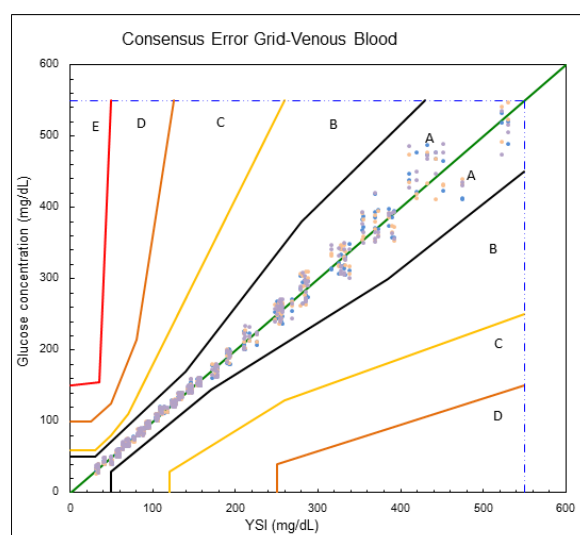
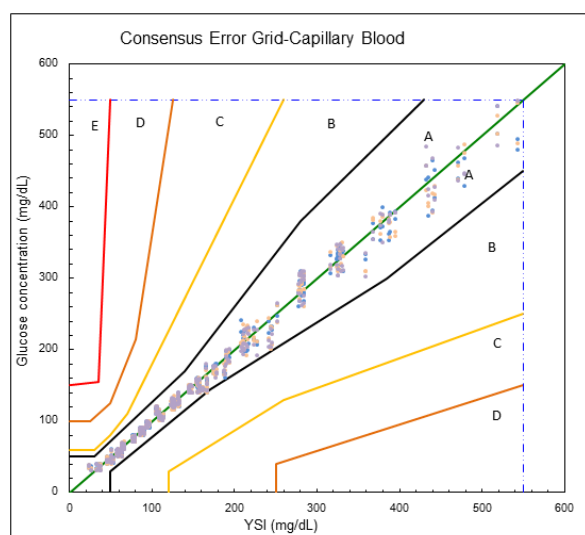
## Summary

- The clinical accuracy study followed the guideline of ISO 15197: 2013 and EN ISO 15197: 2015.
- Clinical data demonstrated PLUS Mini met the current accuracy standards of ISO 15197: 2013 and EN ISO 15197: 2015.
- Out of total 960 tests, average 98.6% (> 95%) fell in the range of  $\pm 15$ mg/dL or  $\pm 15\%$  ( $\pm 0.83$  mmol/L or  $\pm 15\%$ ) from the reference value.
- The study showed the accuracy performance of PLUS Mini monitoring system could be used on healthcare professionals and self-testing.

## Capillary & venous test results

- When the sample < 100mg/dL, 100% of the sample fell within  $\pm 15$  mg/dL
- When the sample  $\geq 100$ mg/dL, 98% of the sample fell within  $\pm 15\%$

Test strip lot	n	$\pm 15$ mg/dL or $\pm 15\%$ ( $\pm 0.83$ mmol/L or $\pm 15\%$ )	n	Within $\pm 15$ mg/dL (Within $\pm 0.83$ mmol/L)	n	Within $\pm 15\%$
<b>Capillary blood testing</b>						
Total	960	947 (98.6%)	312	312 (100%)	648	635 (98.0%)
TD13B105-B0I	320	316 (98.8%)	104	104 (100%)	216	216 (100%)
TD13D215-B0E	320	316 (98.8%)	104	104 (100%)	216	212 (98.1%)
TD13E107-B0D	320	315 (98.4%)	104	104 (100%)	216	211 (97.7%)
<b>Venous blood testing</b>						
Total	960	958 (99.8%)	312	302 (100%)	648	646 (99.7%)
TD13B105-B0I	320	320 (100%)	104	104 (100%)	216	216 (100%)
TD13D215-B0E	320	319 (98.7%)	104	104 (100%)	216	215 (99.5%)
TD13E107-B0D	320	319 (99.7%)	104	104 (100%)	216	215 (99.5%)



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