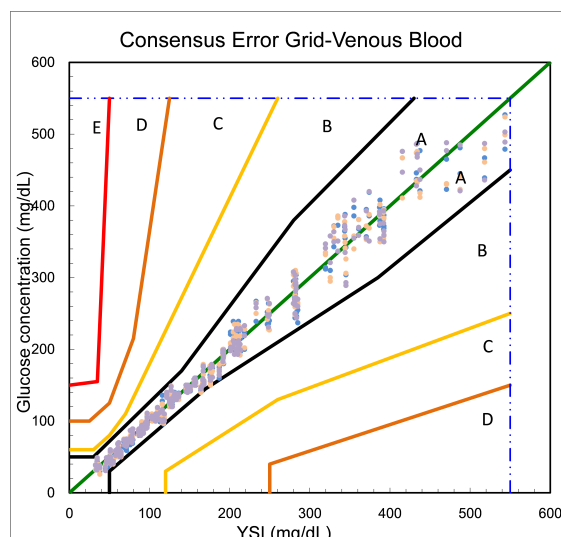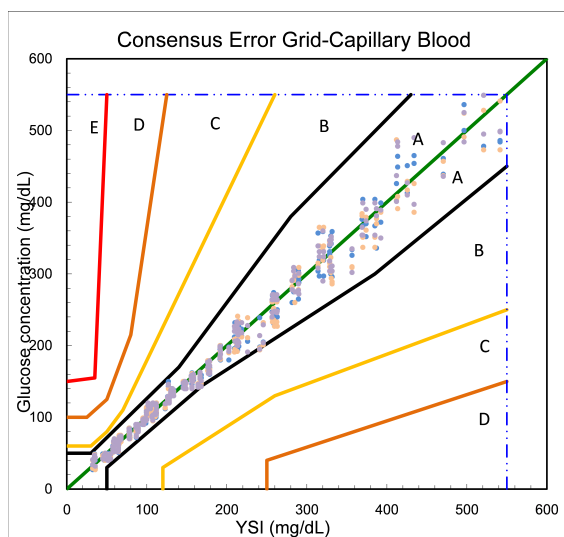# Clinical Data for URiGHT PLUS Talking

Summary

- The clinical accuracy study followed the guideline of ISO 15197: 2013 and EN ISO 15197: 2015.
- Clinical data demonstrated PLUS Talking 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 ± 15mg/dL or ± 15% (± 0.83 mmol/L or ± 15%) from the reference value.
- The study showed the accuracy performance of PLUS Talking 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 ±15 mg/dL
- When the sample ≧ 100mg/dL, 97% of the sample fell within ±15 %

Test strip lot	n	±15 mg/dL or ±15 % (±0.83mmol/L or ±15%)	n	Within ±15 mg/dL (Within ±0.83mmol/L)	n	Within ±15 %
Capillary blood testing						
Total	960	944 (98.3%)	312	312 (100%)	648	632 (97.5%)
TD13B105-B0I	320	316 (98.8%)	104	104 (100%)	216	212 (98.1%)
TD13D215-B0E	320	315 (98.4%)	104	104 (100%)	216	211 (97.7%)
TD13E107-B0D	320	313 (97.8%)	104	104 (100%)	216	209 (96.8%)
Venous blood testing						
Total	960	940 (97.9%)	306	306 (100%)	654	634 (96.9%)
TD13B105-B0I	320	312 (97.5%)	102	102 (100%)	218	210 (96.3%)
TD13D215-B0E	320	315 (98.4%)	102	102 (100%)	218	213 (97.7%)
TD13E107-B0D	320	313 (97.8%)	102	102 (100%)	218	211 (96.8%)

Consensus Error Grid-Capillary Blood

Consensus Error Grid-Venous Blood

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