

Clinical Data for URiGHT PLUS Compact

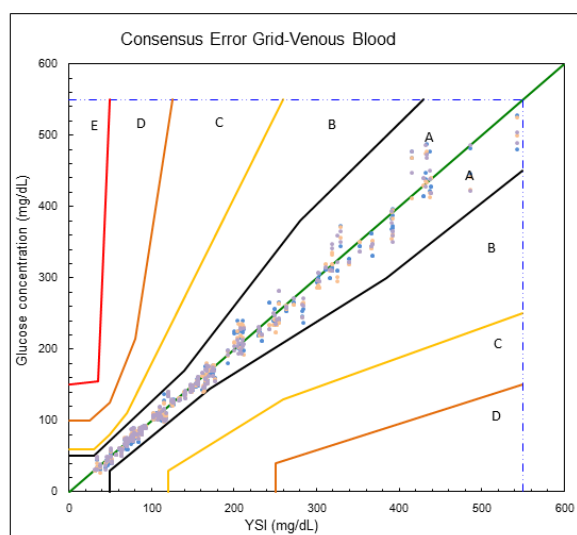
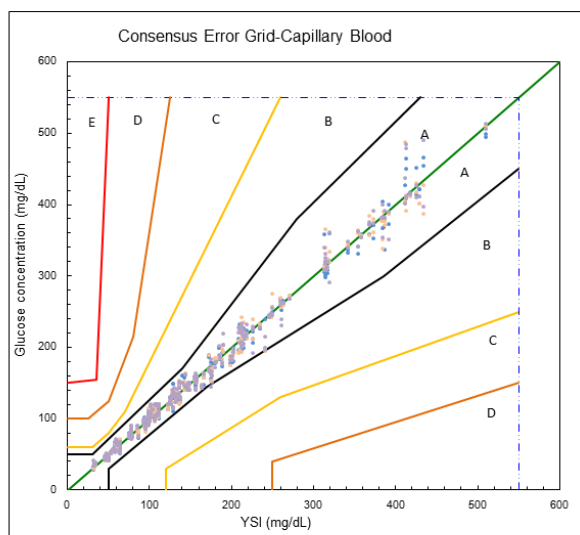
Summary

- The clinical accuracy study followed the guideline of ISO 15197: 2013 and EN ISO 15197: 2015.
- Clinical data demonstrated PLUS Compact met the current accuracy standards of ISO 15197: 2013 and EN ISO 15197: 2015.
- Out of total 960 tests, average 98.5% (> 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 Compact monitoring system could be used on healthcare professionals and self-testing.

Capillary & venous test results

- When the sample $< 100\text{mg/dL}$, 100% of the sample fell within $\pm 15\text{mg/dL}$
- When the sample $\geq 100\text{mg/dL}$, 98% 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 $\pm 15\%$
Capillary blood testing						
Total	960	946 (98.5)	288	288 (100%)	672	658 (97.9%)
TD14F226-B0E	320	316 (98.8%)	96	103 (99.0%)	224	220 (98.2%)
TD14F226-B0G	320	316 (98.8%)	96	103 (99.0%)	224	220 (98.2%)
TD14F227-B0G	320	314 (98.1%)	96	104 (100%)	224	218 (97.3%)
Venous blood testing						
Total	960	948 (98.8%)	306	306 (100%)	654	644 (98.5%)
TD14F226-B0E	320	313 (97.8%)	102	102 (100%)	218	213 (97.7%)
TD14F226-B0G	320	318 (99.4%)	102	102 (100%)	218	216 (99.1%)
TD14F227-B0G	320	317 (99.1%)	102	102 (100%)	218	215 (98.6%)



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