P767 Quantum Blue® Infliximab POC User Performance Evaluation

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BACKGROUND

The objective of the user performance evaluation was to demonstrate the ease-of-use of the Quantum Blue® Infliximab POC system, consisting of the Quantum Blue® Infliximab test and the Dilution Set, to allow non-laboratory professionals to independently and correctly determine infliximab concentrations starting from an existing patients' serum sample within 15 minutes under actual conditions of use and without further laboratory equipment.

METHODS

The ability of point-of-care users to obtain correct results was evaluated by testing result agreement between users' Quantum Blue® Infliximab POC measurements, obtained using three kit lots, in total, and laboratory reference values (RIDASCREEN® IFX Monitoring ELISA (R-Biopharm) for a set of 40 clinical serum samples (Fig. 1). To demonstrate the ease-of-use of the test for non-laboratory professionals, the performance of the users was compared to that of laboratory personnel at BÜHLMANN who performed the same measurements with the Quantum Blue® Infliximab POC system. Test robustness, ease and comfort of use as well as the clearness of the given instructions was further assessed in a questionnaire. Three POC sites, in three geographically distinct locations participated in this study. Operators were non-laboratory medical personnel such as nurses, medical practice assistants or physicians. Two operators were recruited per site. Sites: 1) Hôpital Cantonal Fribourg, Fribourg, Switzerland, 2) Wielospecjalistyczny Szpital Wojewódzki, Gorzów Wlkp, Poland, and 3) Kantonsspital Baselland, Liestal, Switzerland.

RESULTS

None of the six non-laboratory professionals of the three POC sites, received a false-positive or false-negative result, based on an optimal therapeutic window of 3 to 7 µg/mL (Vande Casteele et al., 2015). Overall, non-laboratory professionals at the POC sites received comparable results as the laboratory professionals at BÜHLMANN (Fig. 2 and 3). Bias at 3 and 7 µg/mL, clinical decision points for therapeutic drug monitoring, when compared to laboratory reference values, were determined to 4.8 % and 7.4 % (site 1, Fig. 3), 2.4 % and 5.8 % (site 2) as well as to 12.9 % and 17.0 % (site 3). The total agreement of non-laboratory professionals' results with reference infliximab values was 82.3 % (site 1, Fig. 5), 80.8 % (site 2 , Fig. 6) and 83.8 % (site 3 , Fig. 7) and comparable between sites (Fig. 4). Overall the non-laboratory professionals' assessment of the POC assay in terms of the robustness, ease and comfort of use was very positive.

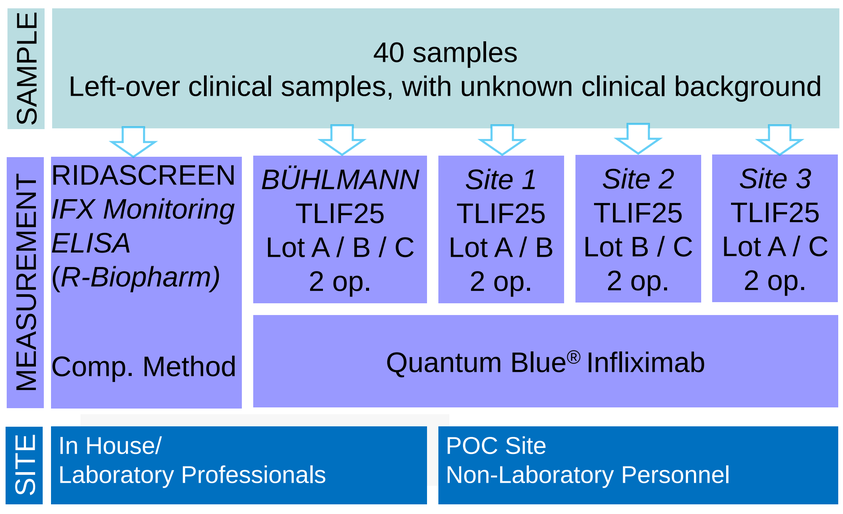

Fig. 1: Study set-up

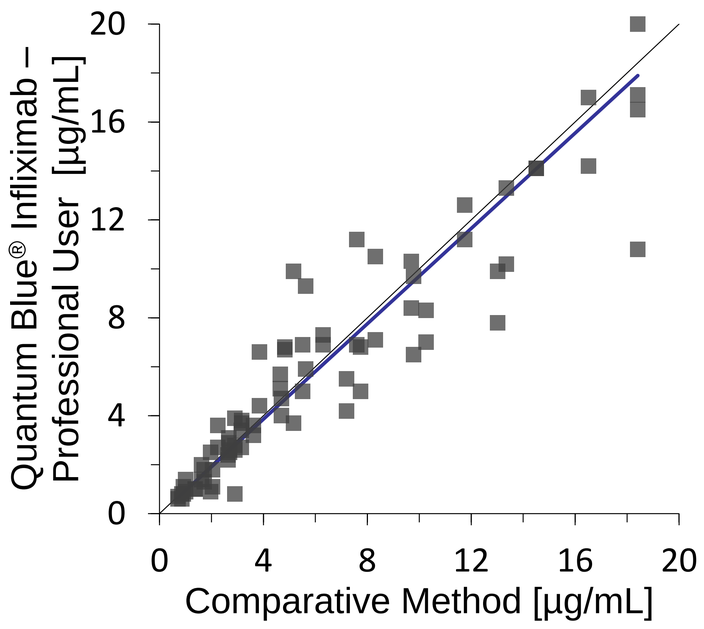

Fig. 2: Passing-Bablok regression analysis of professional users (setting and lots as site 1, slope of 0.97)

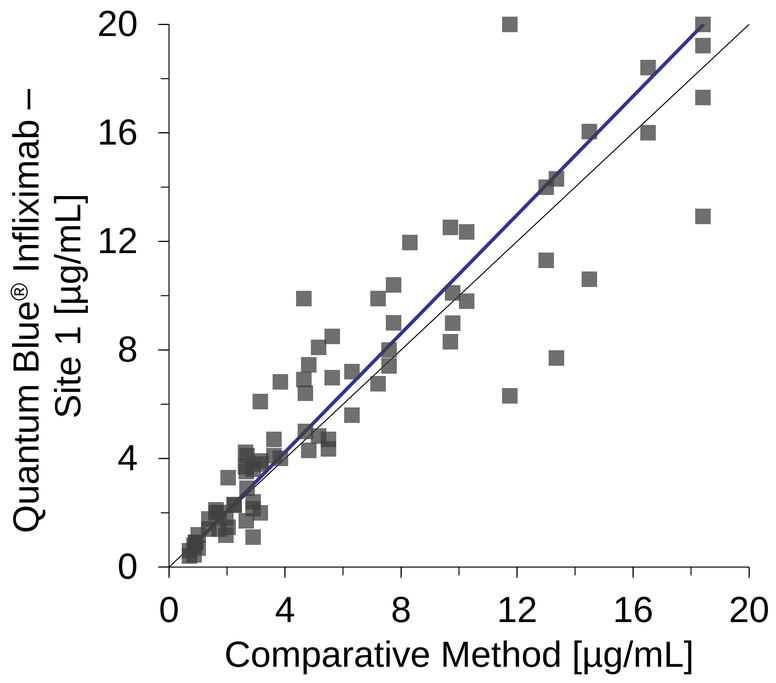

Fig. 3: Passing-Bablok regression analysis for non-laboratory personnel (site 1, slope of 1.09)

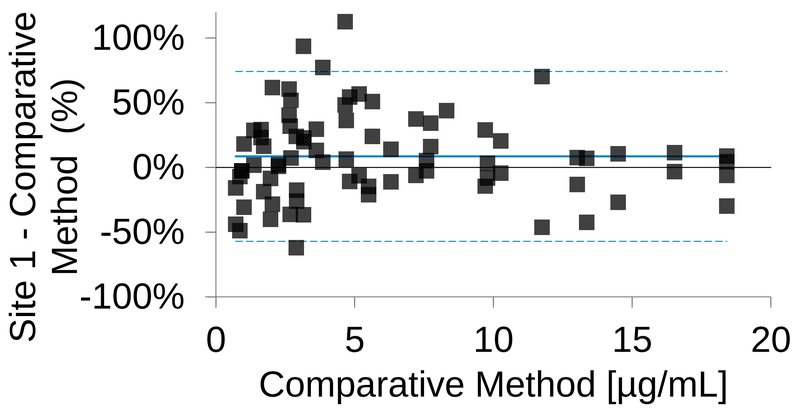

Fig. 4: Bland-Altman analysis (site 1) revealed a bias over the measuring range of 8.58%.

Test		Comparative Method		
	Category	low	optimal	high
Quantum Blue® Infliximab	low	30.4%	1.3%	0.0%
	optimal	7.6%	20.3%	2.5%
	high	0.0%	6.3%	31.6%

82.3%

Fig. 5: Diagnostic agreement for non-laboratory personnel (site 1 vs. comparative method)

Test		Comparative Method		
	Category	low	optimal	high
Quantum Blue® Infliximab	low	26.9%	3.8%	0.0%
	optimal	10.3%	20.5%	1.3%
	high	0.0%	3.8%	33.3%

80.8%

Fig. 6: Diagnostic agreement for non-laboratory personnel (site 2 vs. comparative method)

Test		Comparative Method		
	Category	low	optimal	high
Quantum Blue® Infliximab	low	28.8%	2.5%	0.0%
	optimal	8.8%	22.5%	2.5%
	high	0.0%	2.5%	32.5%

83.8%

Fig. 7: Diagnostic agreement for non-laboratory personnel (site 3 vs. comparative method)

CONCLUSIONS

The outcome of this study suggests that the Quantum Blue® Infliximab POC System, which determines infliximab levels in serum specimens, is easy-to-use, the given instructions are comprehensive, and the results are comparable between different POC sites as well as between POC sites and laboratories.

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