The new infliximab point-of-care quantitative test can equally be used for therapeutic drug monitoring of biosimilars of infliximab

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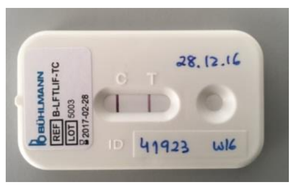
Background and Aims

CT-P13, a biosimilar of the originator infliximab, has been recently approved by the European Medicines Agency (EMA) for the treatment of inflammatory bowel disease (IBD). Therapeutic Drug Monitoring (TDM) is an effective strategy in the management of IBD patients and is widely used in the adjustment of the originator infliximab therapy. A validated point-of-care device for IFX (POC IFX) quantification is already available in the market. The aim of this study was to validate the first point-of-care IFX device for quantification of IFX biosimilar CT-P13 by comparing it with three validated ELISA assays.

Methods

Serum of 184 IBD patients treated with biosimilar infliximab, CT-P13, were analysed for infliximab concentration by POC IFX assay and three ELISA-based established assays. The results were statistically compared both in quantitative and qualitative terms. A statistical analysis of results was performed. Intraclass Correlation Coefficient (ICC) was assessed for quantitative comparison and both accuracy and kappa (95% CI) statistics were used for qualitative analyse. Spiking recovery was also assessed in donors' serum samples spiked with exogenous CT-P13.



Results

Quantitative comparison showed an excellent ICC between POC IFX assay and the three ELISA-based established methods. ICC was 0.907 and 0.935 for POC IFX/in-house and POC IFX/r-biopharm, respectively.

For qualitative comparison, accuracy and kappa (95% CI) statistics were determined after stratification of results by therapeutic interval (<3 ug/mL, 3-7 ug/mL and >7 ug/mL). A good agreement was shown between pairs of assays, as shown in Table 1:

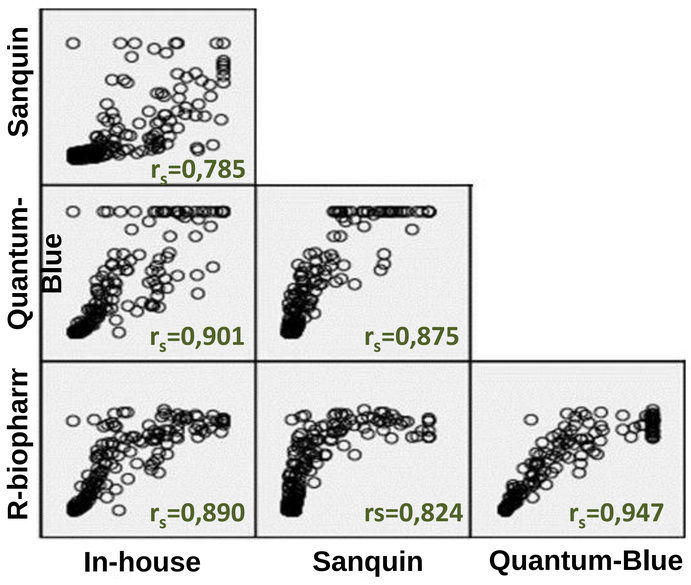


Figure 1 – Spearman Correlation (r_s) between pairs of assays

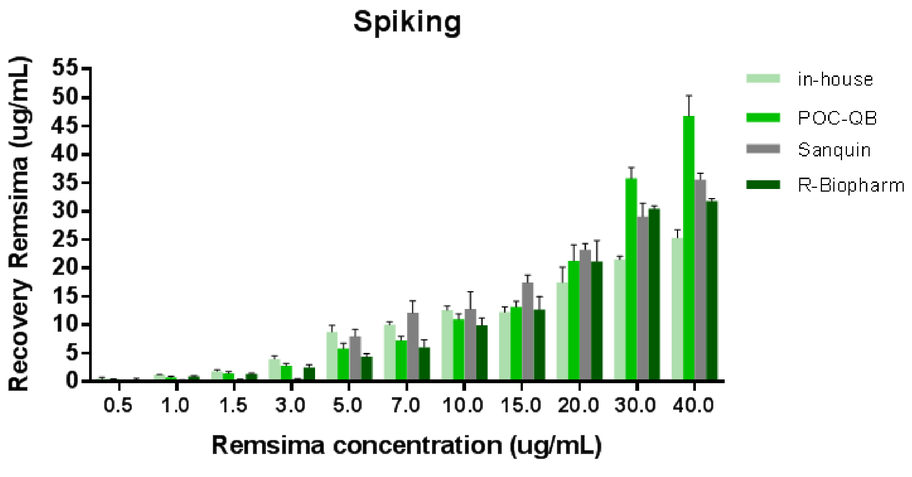
Table 1 : Qualitative comparison between the point-of-care Quantum Blue and the reference assays

		POC -Quantum-Blue			Agreement	
		<3 ug/mL (n)	[3-7ug/mL[(n)	>=7 ug/mL (n)	Accuracy	Kappa [CI95%]
In-House	<3	78	5	1	80%	0,776 [0,177-0,840]
	[3-7[	4	14	20		
	>=7	0	9	54		
Sanquin	<3	79	18	2	80%	0,671 [0,577-0,766]
	[3-7[	3	9	13		
	>=7	0	1	60		
R-biopharm	<3	74	1	0	88%	0,874 [0,824-0,922]
	[3-7[	8	14	1		
	>=7	0	13	74		

POC IFX assay revealed an excellent average spiking recovery percentage (102% [80%-119%]).

Table 2: Average rate (%) for the four assays

	Average Recovery (%)
In-house	109
Quantum-Blue (QB)	102
Sanquin	91
R-biopharm	90



Conclusion

POC IFX assay, a methodology already validated and available in the market to assess IFX originator concentration, showed good agreement with both ELISA-based established assays when used to assess IFX biosimilar. This new methodology, that delivers results in 15 min, should be used as a tool in TDM of CT-P13.