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A successful and cost-effective infliximab therapy for patients suffering from chronic inflammation such as inflammatory bowel disease (IBD) is jeopardized if the drug is not adjusted within an ideal therapeutic window¹. Several methods allow for quantitative determination of infliximab serum levels to achieve therapeutic drug monitoring (TDM) and guide clinical decision-making. Comparability of different infliximab assays is a common issue which needs to be investigated. Here, we examined comparability of the Quantum Blue® Infliximab rapid test to the highly precise HPLC tandem mass spectrometry (LC-MS/MS) method established at Mayo Clinic (USA)².

METHODS

127 blood serum samples from patients receiving infliximab were measured using LC-MS/MS (SCIEX API 5000) at Mayo Clinic² and the Quantum Blue® Infliximab lateral flow based rapid test. The obtained infliximab concentrations from both methods were compared by Passing-Bablok linear regression and Bland-Altman analysis. Furthermore, a precision assessment of the Quantum Blue® Infliximab assay was conducted using spiked human serum samples.

RESULTS

- Passing-Bablok regression revealed a correlation coefficient of $r = 0.965$ and a slope of 0.7632 (Fig. 1).
- Bland-Altman analysis revealed a mean difference of $2.12 \mu\text{g/mL}$ when comparing the rapid test to the LC-MS/MS reference method.
- Precision assessment for the Quantum Blue® Infliximab assay showed 14.2% CV for target level $2.5 \mu\text{g/mL}$, 19.3% CV and 19.1% CV for target levels 8 and $21 \mu\text{g/mL}$ respectively (Fig. 2).
- The two methods present an analytical agreement of 91.3% , 88.2% and 81.1% at commonly used, pathology dependent decision points of $1 \mu\text{g/mL}$, $3 \mu\text{g/mL}$ and $5 \mu\text{g/mL}$ correspondingly (Fig. 3).

CONCLUSION

The Quantum Blue® Infliximab rapid test correlates very well with the LC-MS/MS method and represents a unique and modern analytical tool, for fast time-to-result and simplicity of usage in a more patient near medical environment.

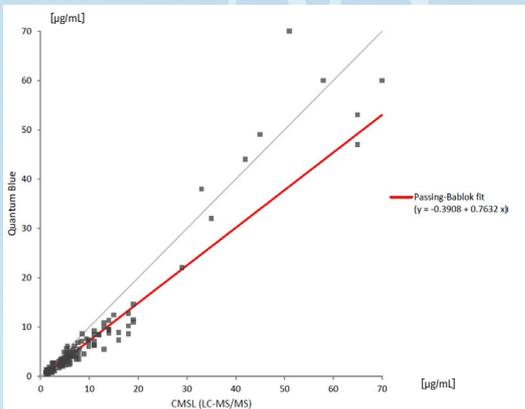


Fig. 1. Passing- Bablok regression analysis

	Level I	Level II	Level III
Target value [µg/mL]	2.5	8	21
Mean [µg/mL]	2.09	7.56	22.70
SD	0.30	1.46	4.33
%CV	14.2%	19.3%	19.1%

Fig. 2. Precision assessment for the Quantum Blue® Infliximab assay.

		Quantum Blue® Infliximab					
		< 1 µg/mL	≥ 1 µg/mL	< 3 µg/mL	≥ 3 µg/mL	< 5 µg/mL	≥ 5 µg/mL
CMSL (LC-MS/MS)	< 1 µg/mL	0	0	36	0	55	0
	≥ 1 µg/mL	11	116	15	76	24	48
		a) Agreement 91.3%		b) Agreement 88.2%		c) Agreement 81.1%	

Fig. 3. Overall analytical agreement to commonly used, pathology dependent decision points of a) $1 \mu\text{g/mL}$, b) $3 \mu\text{g/mL}$ and c) $5 \mu\text{g/mL}$.



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References:

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- ² Willrich M.A. et al., 2015, Quantitation of infliximab using clonotypic peptides and selective reaction monitoring by LC-MS/MS. Int Immunopharmacol. 28(1): 513 - 20