High Correlation of the Quantum Blue® rapid assay with HPLC tandem mass spectrometry for infliximab therapeutic drug monitoring

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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 $2.12 \mu g/mL$ 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 µg/mL, 19.3% CV and 19.1 %CV for target levels 8 and 21 µg/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 µg/mL, 3 µg/mL and 5 µg/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.

References:
¹ Vande Casteele, N. et al., 2015, Trough Concentrations of Infliximab Guide Dosing for Patients with Inflammatory Bowel Disease, Gastroenterology 148: 1320 – 29
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

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