

First successful comparison of Quantum Blue® rapid TDM assay standardization with WHO international standard for infliximab

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Therapeutic drug monitoring of IBD patients under anti-TNF therapy is based on trough level determination of the drug. Rapid assays and multiple ELISAs are available that measure anti-TNF biologics. An international standard is required to improve comparability among different assays. Recently, WHO introduced such a standard for infliximab. Here, we evaluated the correlation of the infliximab WHO standard with BÜHLMANN Quantum Blue® Infliximab standardization.

METHODS

- Calibration curves were generated with BÜHLMANN calibrators and with calibrators made from WHO international standard for infliximab (NIBSC 16/170) (Fig.1).
- Twenty-six serum samples, were analyzed with both calibration curves and compared by Bland-Altman and Passing-Bablok analysis.
- Recovery of six serum samples spiked with WHO international standard for infliximab was determined in Theradiag LISA TRACKER Infliximab (a), Grifols/Progenika Promonitor-IFX (b), Immundiagnostik IDKmonitor Infliximab drug level (c) and BÜHLMANN Quantum Blue® Infliximab (d).

RESULTS

The sample values gained with BÜHLMANN calibrators showed an excellent correlation with values gained with the WHO international standard for infliximab as calibrator.

- Passing-Bablok regression analysis revealed a slope of 0.96 and correlation coefficient (R) of 0.99 (Fig.2).
- Bland-Altman analysis revealed a mean difference in the obtained values of -0.32 µg/mL (-4.42%) (Fig. 3).
- All tests exhibit an excellent mean recovery of 101% (85-114%; a), 99% (91-105%; b); 101% (95-107%; c) and 94% (88-100%, d) (Fig.4).

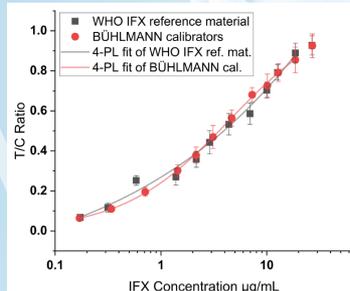


Fig. 1. Calibration curve from WHO IFX reference material and BÜHLMANN calibrators: Ratio of test and control line (T/C ratio) against IFX concentration.

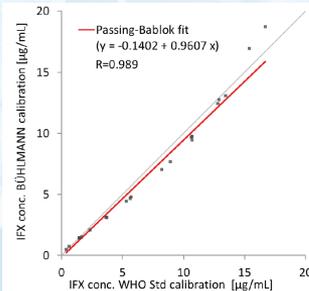


Fig. 2. Passing-Bablok regression analysis of serum samples analyzed with BÜHLMANN and WHO calibration.

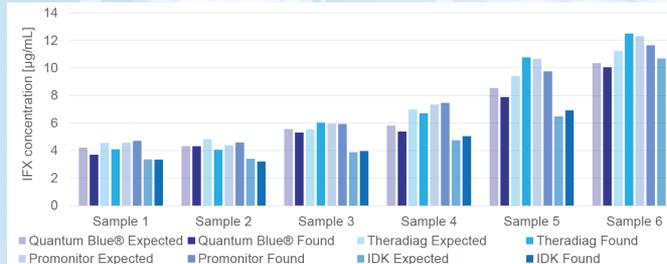


Fig. 4. Spiking recovery analysis of serum samples measured in different ELISAs and one rapid test. Spiking recovery according to Westgard 2008.

CONCLUSION

Current standardization of Quantum Blue® Infliximab rapid test correlates very well with the WHO international standard for infliximab (NIBSC 16/170). This Quantum Blue® Infliximab rapid test represents a unique and modern analytical method, with valid standardization according to WHO for fast time-to-result and simplicity of usage in a more patient near medical environment.

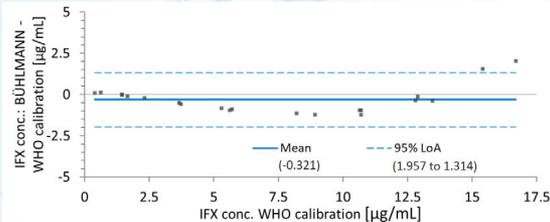


Fig. 3. Bland-Altman analysis of serum samples analyzed with BÜHLMANN calibration curve (Test) and WHO calibration curve (Comparative).



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