P1014 PERFORMANCE OF THE BÜHLMANN QUANTUM BLUE® ADALIMUMAB RAPID TEST DEDICATED FOR THERAPEUTIC DRUG MONITORING OF SERUM ADALIMUMAB TROUGH LEVELS M. Wieser, S. Kräuchi, R. Sokoll, N. Whitehead, F.I. Bantleon, J. Weber, M. Schneider, T.B. Schuster, A. P. Abel **D**BÜHLMANN

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INTRODUCTION

Adalimumab is a human monoclonal antibody used for the treatment of inflammatory diseases like Crohn`s Disease (CD) and Ulcerative Colitis (UC). For efficient treatment trough levels of adalimumab need to be adjusted within a therapeutic window of 5 to 12 µg/mL¹. A rapid test allows a fast analysis of trough levels, providing a great advantage over test formats that need samples to be sent to a central laboratory. Here, we present the analytical performance characteristics as part of the validation of the Quantum Blue[®] Adalimumab lateral flow test from BÜHLMANN.

METHODS

The sandwich lateral flow immunoassay uses a tumor necrosis factor alpha coated label and a highly specific monoclonal antibody to detect adalimumab in a diluted human serum sample. Evaluation was performed according to CLSI guidelines. For linearity, two sample pools, low and high, were blended to obtain 16 concentration levels covering and exceeding the expected measuring range. The blends were assayed in 10 replicates on two test cassette lots. Five pools of clinical adalimumab serum samples were tested over 20 days, in two independent runs with two replicates to establish total precision. Method run per comparison was performed with RIDASCREEN® Monitoring ELISA, (G09043, R-Biopharm, ADM Darmstadt, Germany), based on 130 clinical and contrived (3.1% of total) serum samples, tested in triplicates. For **recovery** six clinical samples over the measuring range were spiked with 5.4 μ g/mL adalimumab in negative serum and compared with the expected values. Samples were measured in 10 replicates with one reagent lot. The high dose hook effect was evaluated with spiked pooled human serum in two runs, the second run with an additional 1:20 dilution of the samples into the measuring interval of the test.



25th UEG Week Barcelona 2017, October 28th – November 1st, Spain (correspondence: ts@buhlmannlabs.ch)

RESULTS

Blue® Adalimumab test Quantum exhibits a linear range of 0.5 - 35.5 µg/mL (Fig. 1). No high dose hook effect was observed up to 800 μ g/mL of adalimumab. Sample dilution linearity was demonstrated to be in the range of 7.6 to 502.8 μ g/mL (Fig. 2). The method comparison (Passing Bablok) revealed a slope of 1.14 and a Pearson's r of 0.87 and is suggesting that the new Quantum Blue® Adalimumab test showed an excellent correlation compared to the ELISA method (Fig. 3). A mean bias of 12.5% was determined using Bland-Altman analysis, while the bias at cut-off 5.0 and 12.0 μ g/mL was 0.3% and 13.8%, respectively. The total within-laboratory precision of the device was between 19.1 and 29.9% with a within-run precision of 16.6 to 28.6% (Table 1). Recovery was between 80 and 90% (Table 2).

CONCLUSION

The Quantum Blue[®] Adalimumab test enables the quantitative determination of adalimumab levels from 1 to 35 µg/mL in serum with a time to result of only 15 minutes. The developed test allows to measure adalimumab over a wide range, well beyond the therapeutic window. Hence, it represents a valuable tool for the clinician to assess adalimumab trough levels.

REFERENCE

. Mitrev, N. et al. Review article: consensus statements on therapeutic drug monitoring of factor therapy necrosis in Aliment. bowel diseases. *Pharmacol. Ther.* (2017). doi:10.1111/apt.14368