

Key Literature – BÜHLMANN Therapeutic Drug Monitoring

BÜHLMANN Quantum Blue® Infiximab papers

- Afonso, J. *et al.*, 2017, Therapeutic drug monitoring of CT-P13: a comparison of four different immunoassay, *Ther Adv Gastroenterol*
“The Quantum Blue kit has the added advantage of being a bedside point-of-care solution, releasing results within 15 min of sampling, and therefore allowing an immediate adjustment of CT-P13 dosing.”
- Afonso, J. *et al.*, 2016, Proactive therapeutic drug monitoring of infliximab: a comparative study of a new point-of-care quantitative test with two established ELISA assays, *Aliment Pharmacol Ther*
“The Quantum Blue IFX assay can successfully replace the commonly used ELISA-based IFX quantification kits...Moreover, it is a user-friendly desktop device that does not require specific laboratory facilities or highly specialised personnel.”
- Magro, F. *et al.*, 2018, The performance of Remicade®-optimized quantification assays in the assessment of Flixabi® levels, *Ther Adv Gastroenterol*
“..., whereas the most accurate method to quantify Flixabi is the Buhlmann (with an ICC of 0.983).”
- Magro, F. *et al.*, 2017, Clinical performance of an infliximab rapid quantification assay, *Ther Adv Gastroenterol*
“Based on this study, we concluded that using the rapid IFX assessment system with a 3 µg/ml threshold is a reliable alternative to the time-consuming enzyme-linked immunosorbent assays in patients on the maintenance phase of IFX.”
- Nasser, Y. *et al.*, 2018, Comparison of Point-of-Care and Classical Immunoassays for the Monitoring of Infiximab and Antibodies Against Infiximab in IBD, *Dig Dis and Sciences*
“...the BÜHLMANN assay which has a broader linear range for trough determination up to 20 µg/mL.”
- Novakovic, V. *et al.*, 2019, Comparison of the Quantum Blue reader Point-of-Care system versus ELISA technique for therapeutic drug monitoring of Infiximab levels, *Clin Biochem*
“When the samples were stratified according to the therapeutic interval, an almost perfect agreement between the methods was observed...In conclusion, our data demonstrate that QB is a suitable alternative to Promonitor IFX for TDM in patients treated with IFX for IBD.”
- Parra, S. *et al.*, 2018, Infiximab Trough Levels and Quality of Life in Patients with Inflammatory Bowel Disease in Maintenance Therapy, *Gastroenterol Res and Pract*
“Quantitative determination of in serum was performed with the Quantum Blue® Infiximab assay... Satisfactory trough levels of infliximab were associated with higher rates of clinical remission, mucosal healing, and improved quality of life in inflammatory bowel disease patients maintenance therapy.”

BÜHLMANN Quantum Blue® Infiximab posters

- Bodini, G. *et al.*, 2019, Therapeutic Drug Monitoring in Crohn's Disease Patients, a Comparison Between Homogeneous Mobility Shift Assay and Point of Care Method, *UEGW 2019 P1750*
“In conclusion, we observed that both POC and HMSA are TL tests able to differentiate relapse and remission in IBD patients...we demonstrated a good concordance between HMSA and POC (Quantum Blue®).”
- Costa Santos, M. P. *et al.*, 2018, Point-of-care infliximab quantification in inflammatory bowel disease in daily practice, *ECCO 2018 P736*
“Point-of-care IFX-TL measurement was easy to implement on a daily practice setting. IFX-TL considered to be within the therapeutic range were found in one-third of patients. In the remaining patients an immediate treatment adjustment could have been made, allowing for resources saving.”
- Lindsj , I. *et al.*, 2016, Patient-near Infiximab trough-level testing by a novel quantitative rapid test: The Quantum Blue Infiximab test, *UEG Week 2016 P1379*
“..., we have shown that such a test can accurately be performed by a nurse. This means that TDM now can be moved from a distant laboratory to the near patient facility...”
- Rentsch, C.A. *et al.*, 2018, Pharmacist-led proactive therapeutic drug monitoring with infliximab (PROXIMO): utility of and cost-saving with the use of a rapid assay for assessing drug level, *ECCO 2018 P428*
“Trough concentrations were assessed via the B hlmann rapid test immediately prior to each infusion... The rapid test is accurate...Its application in the setting of maintenance therapy led to dose adjustment in 3 of 4 patients and higher rates of therapeutic levels, implying standard weight-based dosing is inadequate.”
- Restellini, S. *et al.*, 2018, A pilot study using point of care testing for infliximab and fecal calprotectin in inflammatory bowel patients with a secondary loss of response, *ECCO 2018 P711*
“Using POC testing for IFX patients with a secondary LOR is clinically useful, correlates well with standardized testing, allows for immediate appropriate management of patients and results in a rapid clinical remission as early as 4 weeks.”

- Schuster, T. B. *et al.*, 2016, Performance of the BÜHLMANN Quantum Blue® Infiximab point-of-care assay dedicated for therapeutic drug monitoring of serum infliximab trough levels, *ECCO 2016 P242*

“The BÜHLMANN Quantum Blue® Infiximab assay enables the quantitative determination of the infliximab trough level in serum within 15 minutes and exhibits an excellent correlation with existing ELISAs.”

BÜHLMANN Quantum Blue® Adalimumab papers

- Laserna-Mendieta, E. J. *et al.*, 2019, Comparison of a new rapid method for the determination of adalimumab serum levels with two established ELISA kits, *Clin Chem Lab Med*

“The agreement among the three assays to identify patients with subtherapeutic concentrations of ADA (either below 5 µg/mL or 7.5 µg/mL) was high.”

- Rocha, C. *et al.*, 2019, Accuracy of the new rapid test for monitoring adalimumab levels, *Ther Adv Gastroenterol*

“In conclusion, the Quantum Blue® Adalimumab is a reliable alternative to the commonly used ELISA-based ADL quantification kit. In fact, the rapid test allows a fast and accurate assessment of ADL levels, which in turn contributes towards proactive and cost-effective therapeutic management of IBD patients.”

BÜHLMANN Quantum Blue® Adalimumab posters

- Afonso, J. *et al.*, 2018, Therapeutic Drug Monitoring of Adalimumab: a comparative study of a new point-of-care quantitative test with three established ELISA assays, *UEG Week 2018 P0945*

“The new and first POC-ADA rapid test, which is able to deliver results within 15 min, can be safely used to replace the commonly used ELISA-based ADA quantification kits.”

- Bantleon, F. I. *et al.*, 2017, Quantum Blue® Adalimumab: Development of the first point of care rapid test for therapeutic drug monitoring of serum adalimumab levels, *ECCO 2017 P283*

“The BÜHLMANN Quantum Blue® Adalimumab assay enables the quantitative determination of adalimumab trough level in serum with a time to result of only 15 minutes.”

- Lindsjø, I. *et al.*, 2018, Patient-near Adalimumab trough-level testing by a novel quantitative rapid test: The Quantum Blue Adalimumab test, *UEG Week 2018 P1580*

“In this investigation, we document a close correlation between a 15-minute rapid test for ADA trough-level with that of a standard laboratory assay. We have also shown the robustness of this test since a nurse can accurately perform it.”

General TDM Literature

Infiximab trough level in IBD

- Castele, N. V. *et al.*, 2015, Trough Concentrations of Infiximab Guide Dosing for Patients With Inflammatory Bowel Disease, *Gastroenterology*

“The predefined optimal interval of 3–7 µg/mL for infliximab TCs is applicable for responder patients treated with maintenance infliximab therapy.”

Adalimumab trough level in IBD

- Roblin, X. *et al.*, 2014, Association Between Pharmacokinetics of Adalimumab and Mucosal Healing in patients With Inflammatory Bowel Disease, *Clin Gastroenterol and Hepatol*

“An absence of mucosal healing was associated with trough levels of adalimumab less than 4.9 µg/mL...”

- Ungar, B. *et al.*, 2016, Optimizing Anti-TNF-α Therapy: Serum Levels of Infiximab and Adalimumab Are Associated With Mucosal Healing in Patients With Inflammatory Bowel Diseases, *Clin Gastroenterol and Hepatol*

“...the association between higher level of adalimumab and increased rate of mucosal healing reached a plateau at 12 µg/mL.”

General Recommendations for Therapeutic Drug Monitoring

- Mitrev, N. *et al.*, 2017, Review article: consensus statements on therapeutic drug monitoring of anti-tumour necrosis factor therapy in inflammatory bowel disease, *Aliment Pharmacol Ther*

“To achieve clinical remission in luminal IBD, infliximab and adalimumab trough concentrations in the range of 3-8 and 5-12 µg/mL, respectively, were deemed appropriate.”