



# BÜHLMANN Quantum Blue® Therapeutic Drug Monitoring References

- Schuster. T *et al. ECCO 2016*. Performance of the BÜHLMANN Quantum Blue® Infiximab point-of-care assay dedicated for therapeutic drug monitoring of serum infliximab trough levels.  
“Quantum Blue Infiximab assay enables the quantitative determination of the infliximab trough level in serum with a time to result of only 15 minutes and exhibits an excellent correlation with existing ELISAs”
- Afonso. J *et al. Alimentary Pharmacology and Therapeutics 2016*. Proactive therapeutic drug monitoring of infliximab: A comparative study with a new point of care quantitative test with two established ELISA assays.  
“The Quantum Blue IFX assay can successfully replace the commonly used ELISA-based IFX quantification kits. This point-of-care IFX assay is able to deliver the results within 15 minutes makes it ideal for an immediate target concentration adjusted dosing. Moreover, it is a user-friendly desktop device that does not require specific laboratory facilities or highly specialised personnel”
- Margo. F *et al. Therapeutic Advances in Gastroenterology 2017*. Clinical performance of an infliximab rapid quantification assay.  
“using the rapid IFX assessment system with a 3µg/ml threshold is a reliable alternative to the time consuming ELISA assays in patients on the maintenance phase of IFX”
- Wieser. M *et al. UEGW 2017*. Performance of the BÜHLMANN Quantum Blue Adalimumab rapid test dedicated for therapeutic drug monitoring of serum adalimumab trough levels.  
“The Quantum Blue adalimumab test enables the quantitative determination of adalimumab levels from 1 to 35µg/ml in serum with a time to result of only 15 minutes”
- Afonso. J *et al. Therapeutic Advances in Gastroenterology 2017*. Therapeutic drug monitoring of CT-P13: a comparison of four different immunoassays.  
“The QB 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”
- Bantleon. F *et al. ECCO 2017*. Quantum Blue Adalimumab: Development of the first point of care rapid test for therapeutic drug monitoring of serum adalimumab levels.  
“The developed assay allows to measure adalimumab over a wide range. Hence it represents a valuable tool for the clinicians to assess the adalimumab trough level”
- Fellay. B *et al. ECCO 2018*. Quantum Blue Infiximab POC user performance evaluation. Quantum Blue infliximab POC system which determines infliximab levels in serum specimens, is easy-to-use, the given instructions are comprehensive, and the results are comparable between different POC sites as well as between POC sites and laboratories”
- Restellini. S *et al. ECCO 2018*. A pilot study using point of care testing for infliximab and fecal calprotectin in inflammatory bowel disease patients with a secondary loss of response.  
“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”

- Rentsch. C et al. ECCO 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.  
“This rapid test strategy has the potential to reduce patient risks and improve patient outcomes without negative cost implications”
- Strik. A et al. ECCO 2018. Validation of the Quantum Blue Infliximab level rapid test in clinical practice of patients with inflammatory bowel disease.  
“It is a good alternative for the conventional ELISA method for the measurement of IFX serum concentrations at trough in IBD patients receiving IFX maintenance treatment”
- Nasser. Y et al. *Digestive Diseases And Science* 2018. Comparison of point-of-care and clinical immunoassays for the monitoring of infliximab and antibodies against infliximab in IBD.  
“These are not in fact real point-of-care assays as defined for diabetes testing but rather quick assays. These two tests present two main advantages over ELISA techniques: Firstly, shorter time to obtain results, which would theoretically allow clinicians to rapidly optimize patients’ treatments and improve clinical care, and secondly the possibility to analyze single samples on demand while the ELISA methods lengthen the time-to-result by working in series”
- Lim. M et al *J of Gastroenterology & Hepatology* 2022. Infliximab trough levels: A comparison between the Quantum Blue Infliximab assay and the established ELISA.  
“The QB-IFX had excellent sensitivity and specificity for IFX levels < 2 obtained with the established ELISA. Therefore, QB-IFX could be used for real time dosing decisions when the IFX level is low and dose escalation is required.”
- Bertani. L et al. ECCO 2019. Therapeutic drug monitoring as predictive marker of mucosal healing in Crohn’s disease patients treated with anti-TNF: A prospective multicentre study.  
“Trough level assessment, especially at week 22, could be very useful in the management of CD patients naïve to anti-TNFs treated with ADL.... POC assay has showed the same efficacy than ELISA and is quicker and easier to perform”
- Afonso. J et al. *Advances in Gastroenterology* 2019. Accuracy of the new rapid test for monitoring adalimumab levels  
“Overall, the lateral flow Quantum Blue® Adalimumab rapid test, and the different ELISAs measure similar levels of ADL at low concentrations but diverge at concentrations above 20µg/ml”
- Afonso. J et al. ECCO 2019. Accuracy of a new rapid test assay for monitoring adalimumab levels.  
“The new Quantum Blue Adalimumab assay, which is able to deliver results within 15 minutes, can safely replace the commonly used ELISA based ADA quantification kits and it is reliable alternative to these methods. This new assay is perfect for immediate concentration adjusted dosing avoiding delays caused by ELISA assays....”
- Keller. E et al *UEGW virtual* 2020. First successful comparison of Quantum Blue rapid TDM assay standardisation with WHO international standard for infliximab.  
“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”
- Olson. R et al. *UEGW virtual* 2020. High correlation of the Quantum Blue rapid assay with HPLC tandem mass spectrometry for infliximab therapeutic drug monitoring.  
“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”

- Bodini. G *et al. European Journal of Gastroenterology & Hepatology 2021*. Therapeutic drug monitoring in Crohn's disease patients treated with anti-TNF: a comparison of two techniques.  
"Both POC and HMSA assays are able to reliably differentiate relapse and remission phases in Crohn's disease patients treated with anti-TNF. These techniques showed good concordance and we feel that their preferential use should be based on local accessibility, physicians experience and preference and the need for timeliness availability of results".  
Uses adalimumab and infliximab assays.
- Sdepanian. V *et al ESPGHAN virtual 2021*. Serum infliximab in children and adolescents with inflammatory bowel disease: Comparative analysis between rapid quantification test and ELISA test.  
"Quantum Blue Infliximab rapid test is a reliable alternative to the ELISA gold standard method"
- Sdepanian. V *et al ESPGHAN virtual 2021*. Serum infliximab level using rapid test on pediatric inflammatory bowel disease and its correlation with disease activity index, CRP, fCAL and colonoscopy.  
"The serum infliximab level of the Quantum Blue® Infliximab rapid test correlated with disease activity index, C-reactive protein, fecal calprotectin and colonoscopy, and it was possible to determine the cut-off point of 1.05 µg/mL for this test"
- Brosi. L *et al ECCO 2023*. Novel capillary blood POC test for Adalimumab and Infliximab trough levels: Effects of abnormal blood conditions on the test results.  
"No systemic interferences were detected with treated EDTA whole blood samples, which could appear when using blood as analyte matrix. The excellent agreed to serum trough levels shows that the POC adalimumab/infliximab whole blood assays are ideal for TDM analysis at a clinician's office or infusion clinic."
- Ricken. B *et al ECCO 2024*. Feasibility study of a Point-of-Care assay for rapid determination of anti-TNFα biologics in capillary blood.  
"The newly developed rapid Quantum Blue® assays for the determination of infliximab and adalimumab in capillary blood and EDTA whole blood are very well comparable to the analysis of either biologic in serum. This study furthermore demonstrated the assays are well suited to be used in a POC setting, such as infusion centres."

## Use in clinic:

- Lindsjo. I *et al. UEGW 2016*. Patient-near infliximab trough-level testing by a novel quantitative rapid test: The Quantum Blue Infliximab test.  
"the test can accurately be performed by a nurse which means that TDM now can be moved from a distant laboratory to the near patient facility like the infusion centre and ensure correct dosing in IBD and other patients on IFX treatment"
- Costa Santos. M *et al. ECCO 2018*. Point-of-care infliximab quantification in inflammatory bowel disease in daily practice.  
"POC IFX-TL measurement was easy to implement on a daily clinical 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 resource saving"
- Lindsjo. I *et al. UEGW 2018*. Patient-near Adalimumab trough-level testing by a novel quantitative rapid test: the Quantum Blue Adalimumab test.  
"TDM now can be performed in a near patient facility like an IBD nurse in an out-patient clinic without any significant delay"

## Use with Biosimilars:

- Afonso. J *et al.* *ECCO 2017*. The new infliximab point-of-care quantitative test can equally be used for therapeutic drug monitoring of biosimilars of infliximab.  
“POC IFX assay revealed an excellent average spiking recovery percentage 102%”
- Magro. F *et al.* *ECCO 2018*. The new biosimilar of infliximab SB2 can be quantified by IFX-optimised therapeutic drug monitoring assays.  
“The tested assays can be safely used to monitor drug levels in patients medicated with IFX biosimilar SB2”
- Magro. F *et al.* *ECCO 2018*. The new biosimilar of infliximab SB2 can be quantified by IFX-optimised therapeutic drug monitoring assays.  
“The tested assays can be safely used to monitor drug levels in patients medicated with IFX biosimilar SB2”
- Anchling. L *et al.* *Virtual UEGW 2021*. Serum levels of infliximab and adalimumab biosimilars can be measured equivalently to originator drugs by Quantum Blue rapid testing as tool for therapeutic drug monitoring.  
“The Quantum Blue® Infliximab and Quantum Blue® Adalimumab rapid tests are capable to detect quantitative trough levels of infliximab GP1111 and adalimumab-adaz biosimilars. Therefore, these tests offer equivalent quantification of infliximab and adalimumab originator drugs, as well as their biosimilars GP1111, SB2, CT-P13 and adalimumab-adaz allowing for identification of patients with suboptimal drug levels as part of their therapeutic drug monitoring”.

## Anti-Drug Antibodies:

- Ricken. B *et al.* *ECCO 2019*. Quantum Blue Anti-adalimumab: Development and evaluation of a point of care rapid test for measuring anti-infliximab antibodies in human serum.  
“The Quantum Blue Anti-adalimumab rapid test allows a fast detection of anti-adalimumab antibodies in human serum samples”
- Bantleon. F *et al.* *ECCO 2019*. Quantum Blue Anti-infliximab: Development and evaluation of a point of care rapid test for measuring anti-infliximab antibodies in human serum.  
“Quantum Blue Anti-infliximab test allows the fast and easy detection of anti-infliximab antibodies in human serum within 15 minutes”
- Bantleon. F *et al.* *ECCO 2019*. Quantum Blue Anti-infliximab: Development and evaluation of a point of care rapid test for measuring anti-infliximab antibodies in human serum.  
“Quantum Blue Anti-infliximab test allows the fast and easy detection of anti-infliximab antibodies in human serum within 15 minutes”