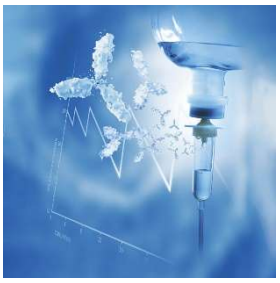

BÜHLMANN Quantum Blue® Therapeutic Drug Monitoring References

- 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"
- 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"
- 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…. QB 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”
- 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 QB 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”

Use with Biosimilars:

- 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”.