**Comparison of Sb2-Infliximab with Originator-Infliximab in the Measurement of Serum Concentrations**

**A Short Communication**

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# Abstract

**BACKGROUND:**

The optimal use of infliximab depends on the measurement of trough levels with subsequent appropriate dose adjustment. With the introduction of biosimilars, it is important to demonstrate that the biosimilar behaves similarly in the assay utilized as the originator-infliximab, for which the assays were developed. In this study, the authors aimed to compare the concentrations of SB2-infliximab (Renflexis®) with that of originator-infliximab (Remicade®) when added to serum from healthy subjects and those with inflammatory bowel disease (IBD) when measured by commonly employed commercial assays.

**Methods:**

Sera from two healthy controls, two patients with ulcerative colitis (one with quiescent disease, one with active disease), and two patients with Crohn's disease (one with quiescent disease, one with active disease) were spiked with SB2-infliximab or originator-infliximab at 0-20 μg/mL. Concentrations were measured using three commonly used assay kits (Lisa-Tracker®, Shikari Q-Inflix®, Promonitor IFX®) and one rapid test (Quantum Blue®). The results were compared using Bland-Altman techniques.

**Results:**

Close agreement was observed between measured concentrations for all assays, irrespective of the origin of the serum. Limits of agreement varied between at worst -0.302 and 0.465 μg/mL, with the mean difference between the molecules being at worst 0.04 μg/mL (95% confidence intervals -0.011, 0.093).

**Conclusions:**

The originator and SB-2 biosimilar-infliximab behaved similarly in several currently utilized assays in terms of their concentrations in biological fluids. Clinicians can be confident that therapeutic drug monitoring using platforms designed and developed for the originator-infliximab can be applied to SB-2-infliximab.