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Feasibility study of a Point-of-Care assay for rapid determination of anti-TNFα biologics in capillary blood

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Introduction

Inflammatory bowel disease (IBD) patients benefit from therapeutic drug monitoring and personalized adjustment of anti-TNFα drugs such as adalimumab (ADL) and infliximab (IFX). Two recently developed rapid tests for the determination of ADL and IFX that only require capillary blood (CB) or EDTA whole blood (WB) are tested in a POC setup at three different study sites.

The primary aim of this study is to demonstrate matrix equivalency of CB and EDTA WB compared to serum as reference

Methods

This observational study was performed at three sites. Two sites in Switzerland, Clarunis Basel and Kantonsspital Baselland, and one site in France, Centre Hospitalier Universitaire de Saint-Étienne. CB and WB sample analysis were performed at the study sites in a POC environment and serum samples either in parallel or in a laboratory. The established Quantum Blue® serum rapid tests and the newly developed capillary blood applications were used. In total samples of 25 patients under IFX therapy and 32 patients treated with ADL were evaluated.

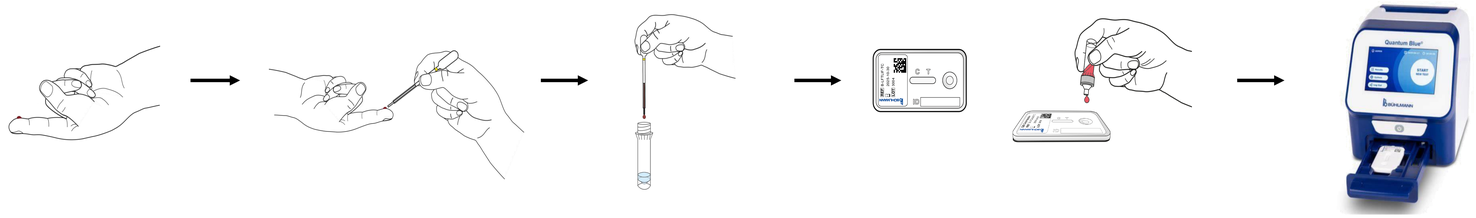

Figure 1: Schematic illustration of the whole blood sampling procedure with Quantum Blue® Adalimumab/Infliximab Capillary Blood using a Quantum Blue® Reader.

Results

Passing-Bablok (Figure 2) and Bland-Altman analysis revealed a good agreement of CB vs serum and WB vs serum for both IFX and ADL sample sets. The mean bias based on Bland-Altman for the biologic's trough level analyzed in CB and compared to serum was as low as 1.8% for IFX and -7.9% for ADL. A comparison of EDTA WB compared to serum revealed a mean bias of -2.0% for IFX and 7.2% for ADL.

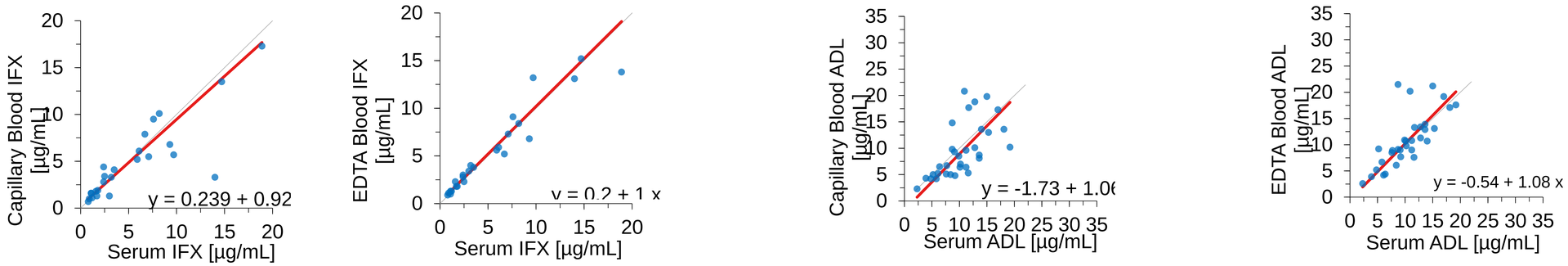

Figure 2: Passing-Bablok
A) IFX analyzed in CB vs. serum
B) IFX analyzed in WB vs. serum
C) ADL analyzed in CB vs. serum
D) ADL analyzed in WB vs. serum

Conclusion

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. This saves sample shipment and analysis in the central laboratory. Both capillary blood assays are standardized to WHO reference material.

Conflict of interest

[1]Authors are employees of BÜHLMANN Laboratories AG

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