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PRELIMINARY COMPARISON BETWEEN ELISA TEST ROUTINELY USED AND FULLY AUTOMATED ELISA MONOTEST SYSTEM IN SOLID-PHASE FOR THE THERAPEUTIC DRUG MONITORING

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Background: Infliximab (IFX) and Adalimumab (ADL) are biological drugs widely used in clinical practice, as anti-tumor necrosis factor (TNF) agents, in patients with inflammatory bowel diseases and rheumatic diseases. Sometimes these drugs fail to produce a satisfactory clinical response often due to the generation of anti-drug antibodies (ADA). Our study aims to compare and verify differences between enzyme-linked immunosorbent assay (ELISA), LISA TRACKER Duo Drug (LISA-Tracker Duo Adalimumab and LISA-Tracker Duo Infliximab) routinely used in our laboratory, and an automated quantitative method, the DIESSE CHORUS TRIO instrument, for the determination of IFX and ADL drugs and ADA levels.

Materials and Methods: The study was performed on 37 patients affected by selected Rheumatology and Gastroenterology diseases, 21 treated with IFX and 16 treated with ADL, attending Rheumatology and Gastroenterology departments at the University of Modena, Italy. All sera were analyzed for IFX, ADL, anti-IFX and anti-ADL using LISA-Tracker Duo Adalimumab and Infliximab (Theradiag) and the fully automated assays CHORUS Promonitor (DIESSE Diagnostica Senese). The level of agreement between two methods was evaluated through Spearman correlation coefficient for drugs determination and through Cohen kappa for anti-drug antibody results. Drugs determination results were analyzed by Bland-Altman plots, to evaluate comparability of the two methods and to estimate the differences.

Results: For the detection of drugs levels, the two methods showed a perfect agreement with Spearman coefficient values of 0.98 (p = 3.37e-14) and 0.96 (p = 2.90e-09) for the dosage of IFX and ADL, respectively. Bland-Altman Plots for detection of IFX levels showing a bias ranging from −8,37 to 18,46 and a standard deviation of difference equal to 1.96 with limits of agreement from −11,90 to 9,42. The scatter of differences through Bland-Altman plot for ADL detection levels showing a bias ranging from −6,89 to 5,17 and a standard deviation of difference equal to 1.96 with limits of agreement from -7,01 to 6,73. Concordance between two methods for the detection of anti-drug antibody levels, assessed by Cohen's kappa test, displayed a good agreement with a value of 0.61 for anti-IFX and 1.0 for anti-ADL.

Conclusion: Our results revealed a strong correlation between methods, but the impact of ELISA is more laborious. CHORUS Promonitor being a mono-test, fully automated and faster, offers timing advantages for laboratory and clinical monitoring. The choice of the method must be made according to the equipment and the workflow of the laboratory.
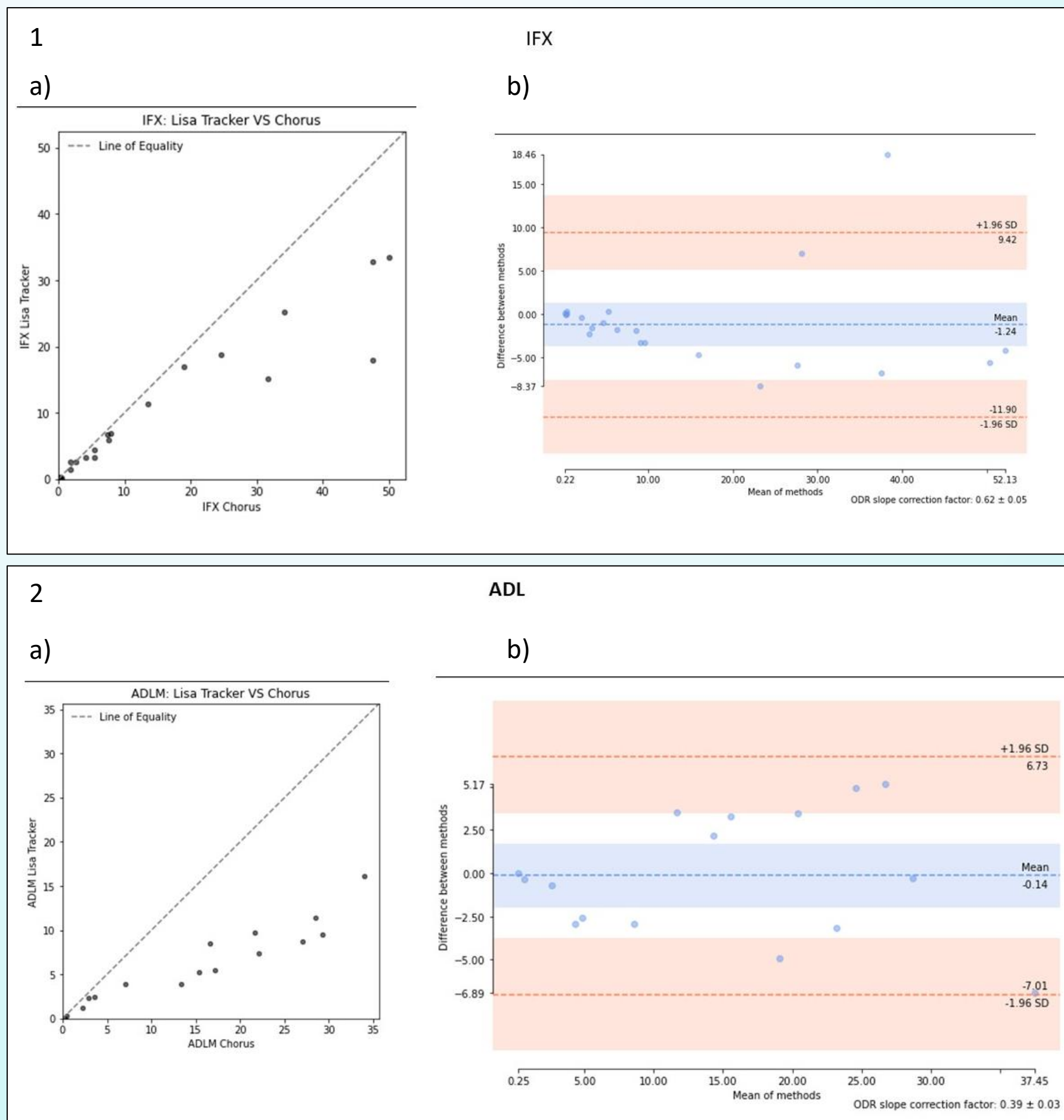

Figure **1a)** Correlation between ELISA and CHORUS for Infliximab (IFX): Spearman coefficient values r = 0.98 (p = 3.37e-14); Cohen's kappa score = 0.61; **1b)** Bland-Altman Plots for detection of IFX levels.
Figure **2b)** Correlation between ELISA and CHORUS for Adalimumab (ADL): Spearman coefficient values r = 0.96 (p = 2.90e-09); Cohen's kappa score = 1.0; **2b)** Bland-Altman Plots for detection of ADL levels.

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