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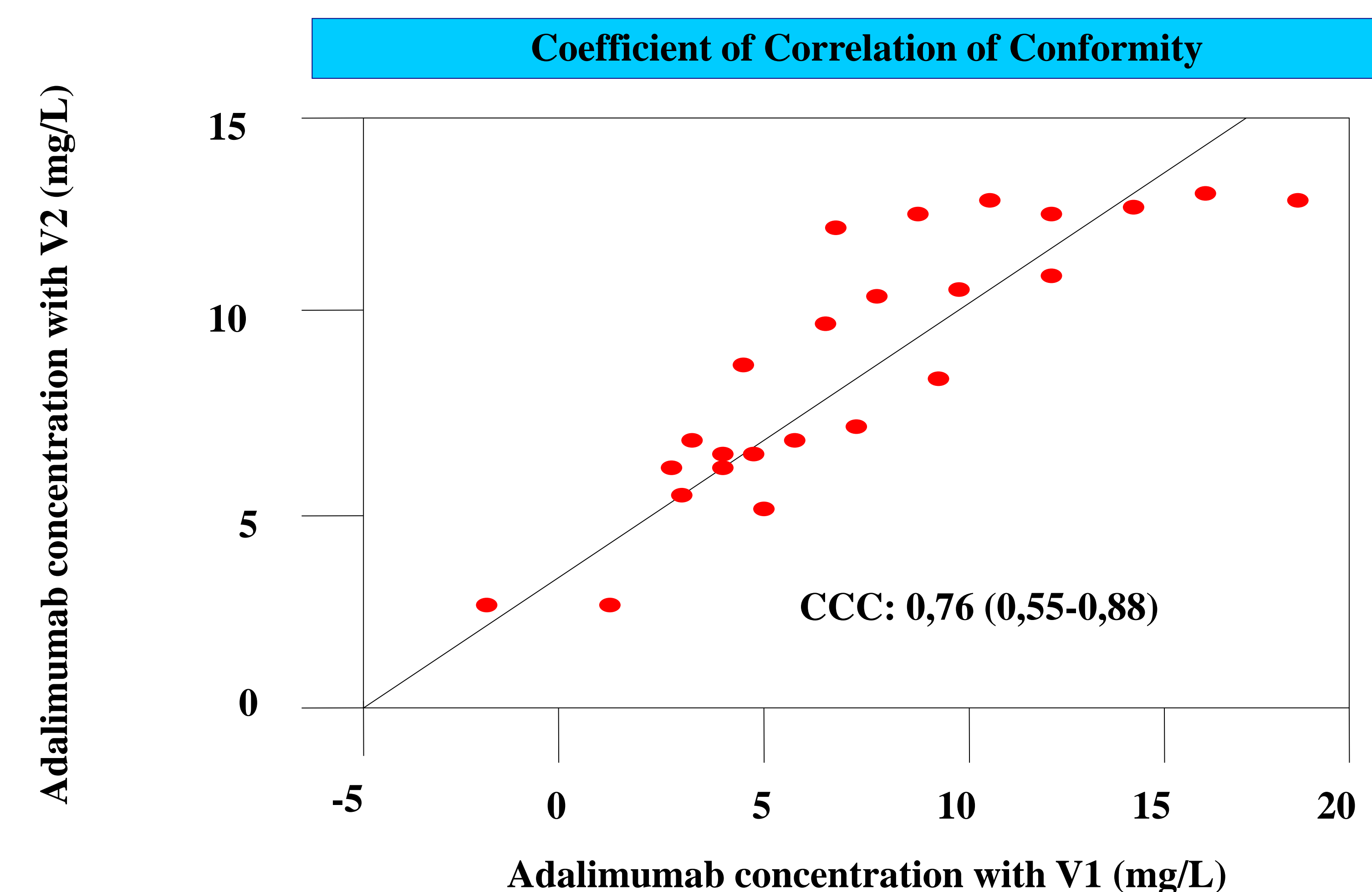
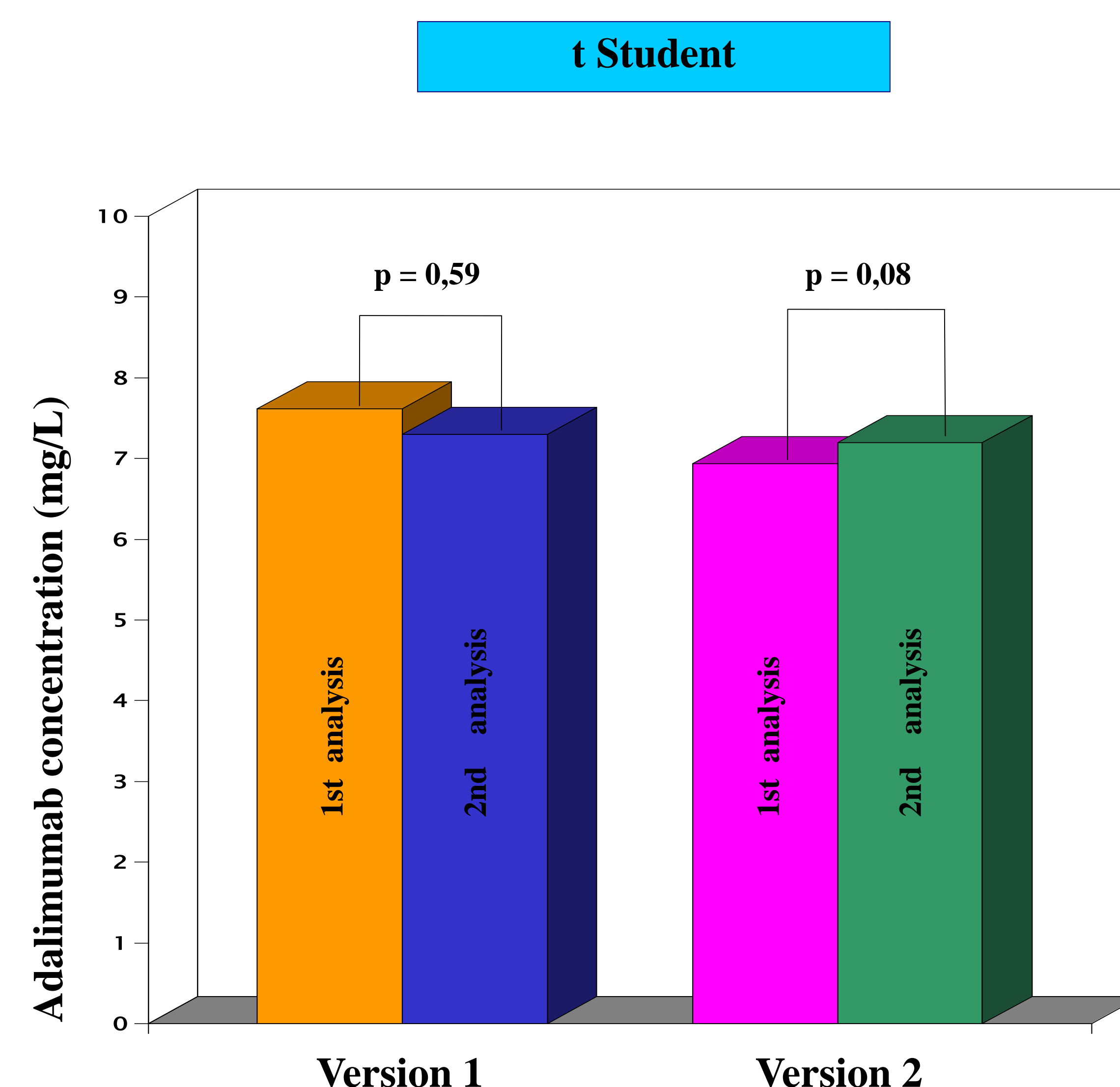
OBJECTIVE

To describe the results obtained of the comparative study between both versions of the ELISA commercialized for therapeutic drug monitoring of Adalimumab (Promonitor®, Proteomika S.L., distributed by Menarini Diagnósticos S.A.®).

PATIENTS AND METHODS

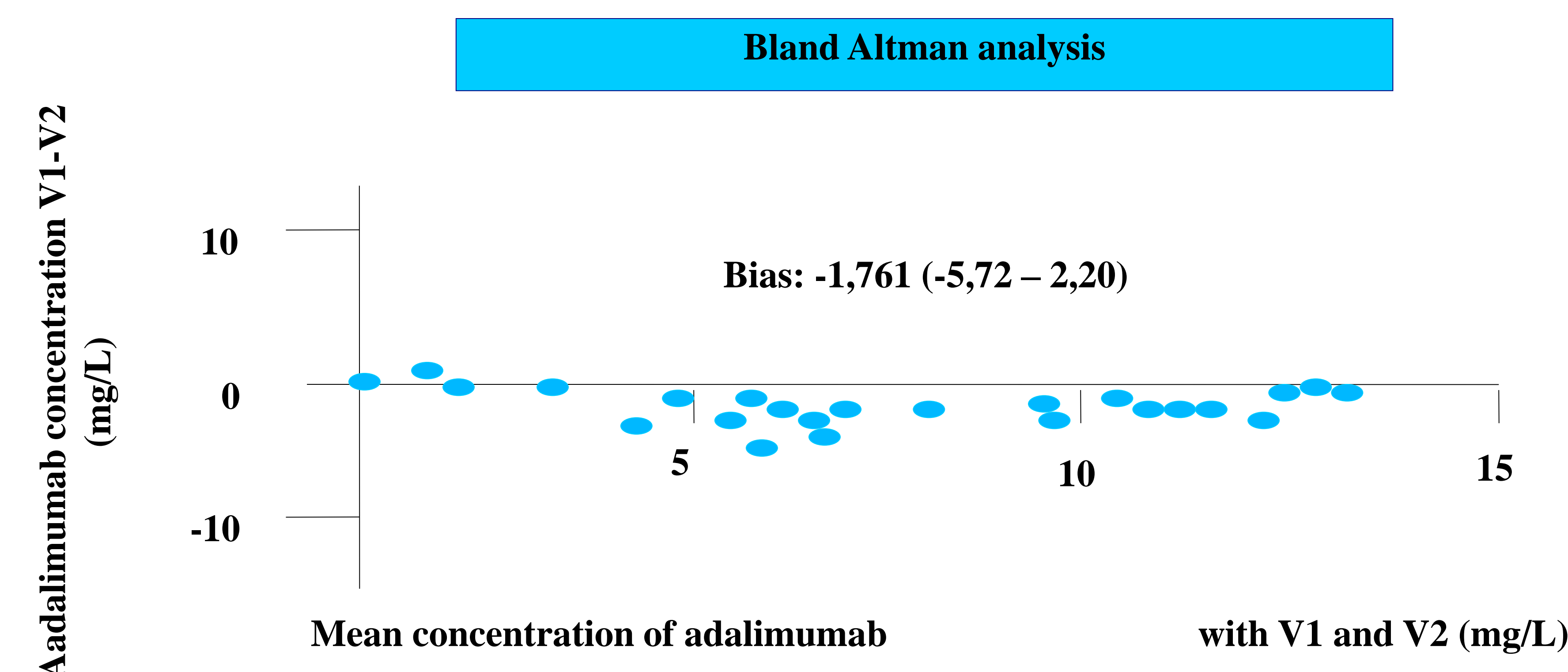
- 24 selected samples of patients with rheumatoid arthritis treated with Adalimumab (ADA).
- With different concentrations of drug that covered the whole analytical range of the assay.
- The samples were extracted just before the administration of ADA and remained frozen to -80°C (trough level).
- They were analyzed for duplicate with both available versions of the ELISA: V1 or previous and V2 or updated.
- Statistical study:
 - t of Student of samples paired to compare ADA's average concentrations between both analysis with the same version of the test.
 - By means of the statistician kappa the conformity was evaluated between the results obtained with the same version.
 - There has been calculated the Coefficient of Correlation of Conformity (CCC) and his interval of confidence to know if the measurements with both versions of the test show conformity.
 - Bland-Altman analysis to value the average difference along the whole measured interval.

RESULTS



Kappa

Version 1	Version 2
0,55 (0,18 – 0,79)	0,91 (0,65 – 1,00)



CONCLUSIONS

1. The V2 of the test provides higher results of ADA's concentration than the V1. Nevertheless, a major precision is observed in the range of near concentrations at the level of clinical decision.
2. The new version of the ELISA allows the complete automation, which simplifies very much the analysis, and reduces significantly the variability in the repetitions of the samples.