

Analytical Validation of the iSED® automated analyzer for Erythrocyte Sedimentation Rate (ESR)

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Objective

Currently at ZLM, the parameter Erythrocyte Sedimentation Rate (ESR) is processed manually in the BD Seditainer™ blood collection tubes and results are manually entered into the LIS. As a result of the recommendation from the International Council for Standardization in Hematology (ICSH) regarding the use of whole blood from standard EDTA blood collection tubes, the company Becton Dickinson (BD) will cease the production and sale of its range of BD Seditainer™ and BD Vacutainer® tubes for ESR analysis as of April 1, 2023. Therefore, we decided to evaluate the analytical performance of the iSED® analyzer as a solution for the automatic processing of the ESR in EDTA tubes with result transfer to the LIS via an interface.

Materials and Methods

Validation was performed according to the recommendation of ICSH which included the method comparison of 60 samples in the analytical range of 15 – 105 mm/h with the gold standard Westergren method, intra-run precision, carryover testing, stability studies and verification of the manufacturer's reference intervals in accordance with the CLSI guidelines.

Results

The iSED® demonstrated acceptable imprecision with minimal carryover (2.14%). Comparison between iSED and Westergren yielded a correlation coefficient of $r = 0.91$, $P > 0.001$, while Passing-Bablok analysis revealed constant and proportional difference with an equation of $y = 8.43 + 1.032 x$, intercept of 8.44 (95% CI: 4.00 – 11.19) and slope of 1.03 (95% CI: 0.93 – 1.18) (Fig. 1). A mean bias of -9.2 (95% CI: -11.6 – -6.7) was obtained with Bland-Altman analysis (Fig. 2). The drift in the lower values in the Bland-Altman plot is acceptable and can be explained by the methodological differences between both methods. The iSED® measurements were stable up to 24 hours when stored at room temperature and at 4-8°C.

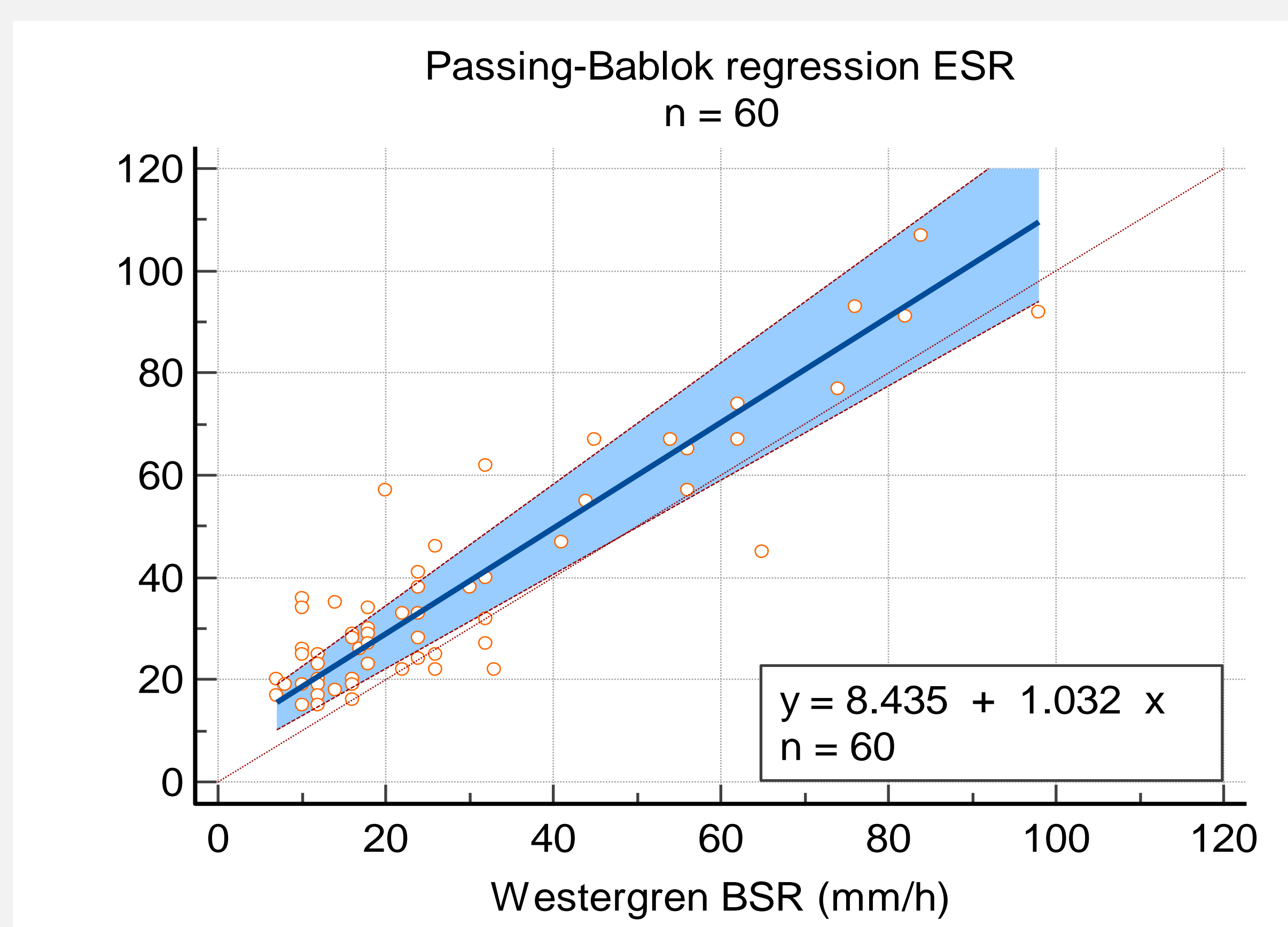


Fig. 1. Passing–Bablok Analysis Results of the comparison of two methods for ESR measurement: iSED and Westergren method.

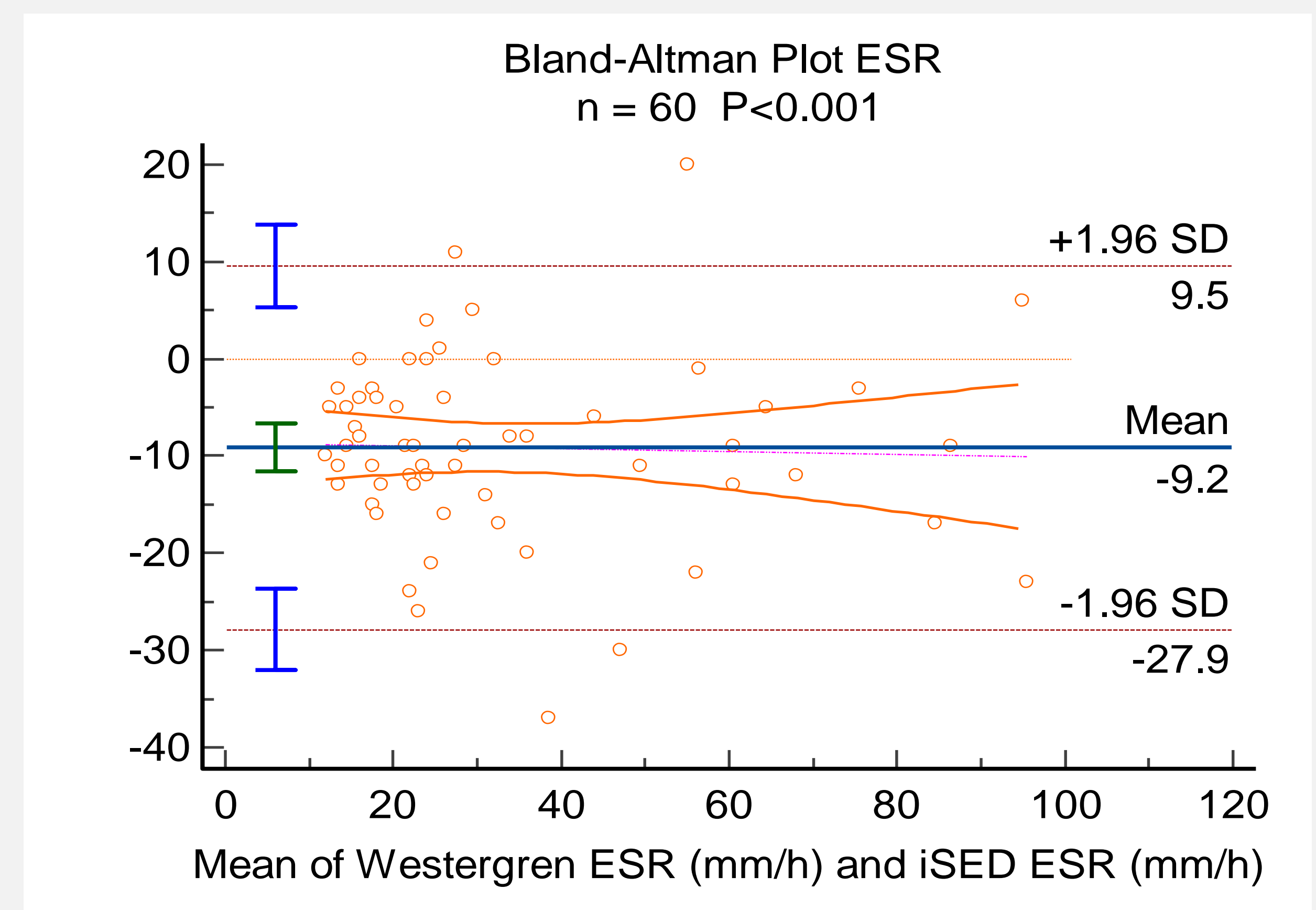


Fig. 2. Bland–Altman plot of the difference between ESR values obtained with Westergren method and iSED against the mean of ESR values in the 60 samples.

Conclusion

This study shows that the iSED® presents a satisfactory precision and comparability with the gold standard Westergren method and confirmed results of recent studies regarding sample stability for 24 hours when stored at either room temperature or refrigerated at 4-8°C. As a result, the iSED® is a suitable replacement for the Westergren method and will be introduced into routine use.