

Evaluation of **VACUETTE**[®] Plastic ESR Tube with the automated ESR measurement on SRS 20/ II

Background:

Greiner-Bio-One, Austria has sold plastic evacuated tubes (**VACUETTE**[®]) for venous blood collection since 1986. In addition to the standard product line, Greiner-Bio-One also has an extensive range of special tubes including tubes for Erythrocyte Sedimentation Rate (ESR) testing. Trisodium citrate is the anticoagulant of choice for the collection of blood specimens intended for the determination of the ESR. The modified method of Westergren is used for assessing the inflammatory disease. The tubes are composed of coated polypropylene. The caps are made of brom butyl rubber.

Study Objective:

A clinical evaluation of the ESR (Erythrocyte Sedimentation Rate) was carried out to assess the **VACUETTE**[®] ESR plastic tubes for their performance in comparison with the **VACUETTE**[®] ESR glass tubes with the automated ESR measurement on the instrument SRS 20/II.

Study design:

The following tube types were used in this study:

- 9 x 120 mm 4 NC ESR Sod. Cit Glass with 1.6 ml draw volume (item # 729093)
- 9 x 120 mm 4 NC ESR Sod. Cit PP-Plastic with 1.5 ml draw volume (item # 729073)

Venous blood was collected from 19 healthy donors and 21 pathological donors using the **VACUETTE**[®] Standard Tube Holder and 21 G Needle. A discard tube was used to guarantee appropriate filling of the tubes. Two tubes were collected from each donor (one 729093 and one 729073), the order of draw was randomized. Directly after blood collection, the tubes were carefully inverted 8 times to allow proper mixing.

The ESR tubes were analyzed immediately (max. 1 hr) after specimen collection. 1 hour and 2 hour Westergren values were determined with temperature correction at 18 °C. The analyses was performed on a Greiner SRS 20/ II instrument. The automated determination of the Greiner instrument has a correlation of 0,983 to the standard Westergren method ^[1].

The 1 hour Westergren value was determined by the 30 minutes automatic measurement, the 2 hour Westergren value determined by the 1 hour automatic measurement ^[1].

Results/ Comments:

Result comparison analyses of the **VACUETTE**[®] ESR glass tube and **VACUETTE**[®] ESR plastic tube was performed for 1 hour and 2 hour Westergren values.

The outlier test (Grubbs test) for normal donor results at 1 hour showed that donor number 15 was an outlier. Therefore this donor was excluded from the statistical tests.

Paired T-test ($\alpha 0,05$) was performed using StatSoft Software, Version 9. No statistical significance was observed between the **VACUETTE**[®] ESR glass tube and the **VACUETTE**[®] ESR plastic tube.

The coefficient of correlation r was used to quantify the linear correlation of the results between the glass and plastic tubes ^[2]. The correlation r between the pathological donor results at 1 hour Westergren was 0,99071 and for the 2 hour Westergren 0,99176. The normal donor results showed a correlation of 0,93438 at 1 hour Westergren and 0,9539 at 2 hour Westergren, which means a high consistency of the ESR results from glass to plastic.

Conclusion:

This test examined the performance of the **VACUETTE**[®] ESR plastic tubes in comparison with the **VACUETTE**[®] ESR glass tubes. **VACUETTE**[®] ESR plastic tubes do not show a significant statistical difference compared to **VACUETTE**[®] ESR glass tubes in terms of Erythrocyte Sedimentation Rate. Consequently it can be proven that the **VACUETTE**[®] ESR plastic tube is a suitable substitute to the current **VACUETTE**[®] ESR glass tube.

References:

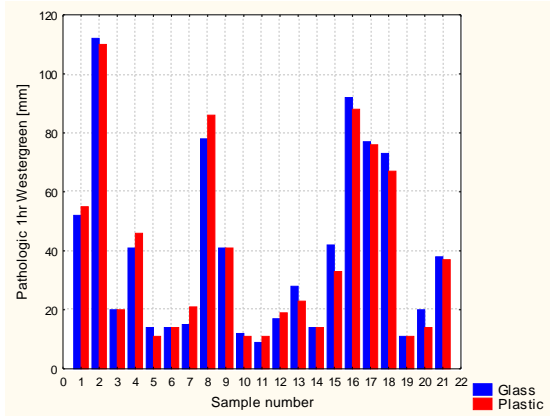
- [1] Koch, P. (2001). Comparison of Manual vs. Automated Blood Sedimentation Test: Quality and Economy. J Lab Med, 25 (5/6), 189-194.
- [2] Weiß, C. (2007). Basiswissen Medizinische Statistik (4. Aufl). Heidelberg: Springer.

Results in detail

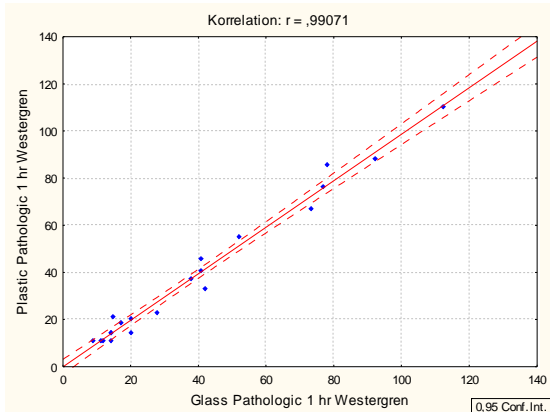
Pathological Donor Results

1 hour Westergren results

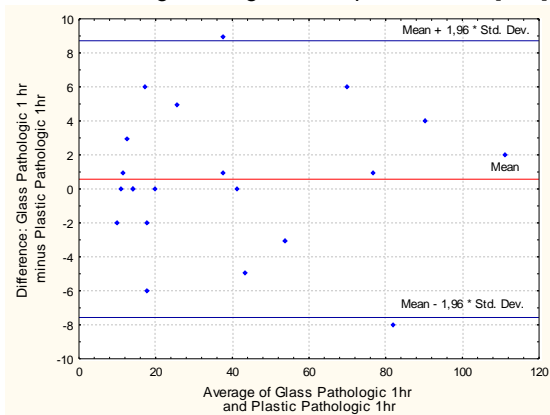
Bar Chart. Pathological donor results at 1 hour Westergren for glass and plastic tubes [mm]:



Regression Line. Pathological donor results at 1 hour Westergren for glass and plastic tubes [mm]:



Bland-Altman plot. Pathological donor results at 1 hour Westergren for glass and plastic tubes [mm]:

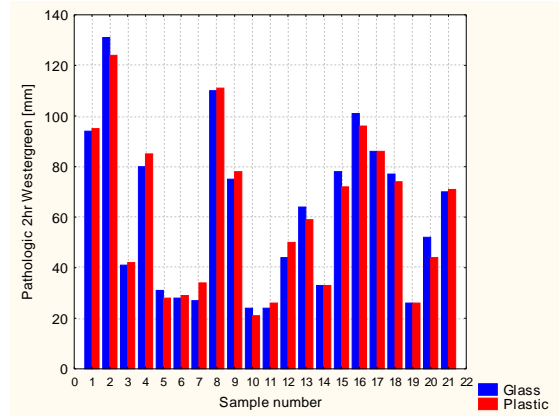


Paired T-Test at a significance level of 5 %:

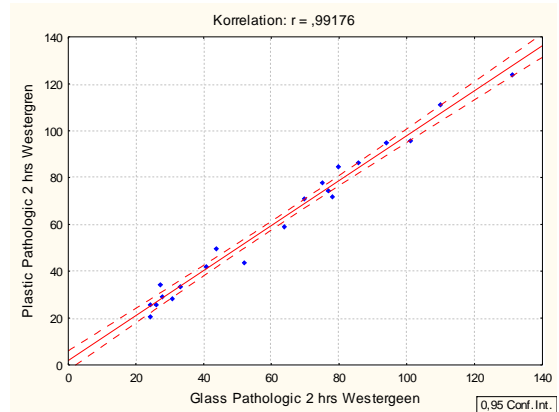
N = 21
P-value = 0,536
No statistical significance

2 hours Westergren results

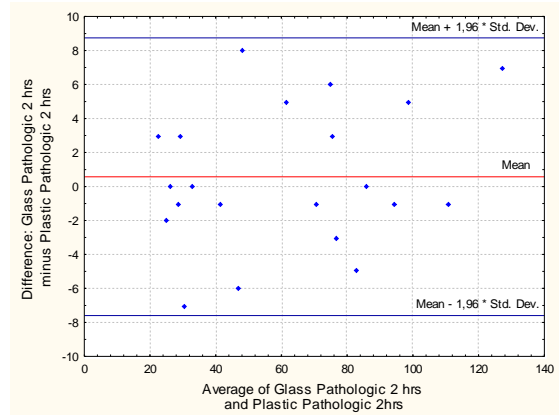
Bar Chart. Pathological donor results at 2 hour Westergren for glass and plastic tubes [mm]:



Regression Line. Pathological donor results at 2 hour Westergren for glass and plastic tubes [mm]:



Bland-Altman plot. Pathological donor results at 2 hour Westergren for glass and plastic tubes [mm]:



Paired T-Test at a significance level of 5 %:

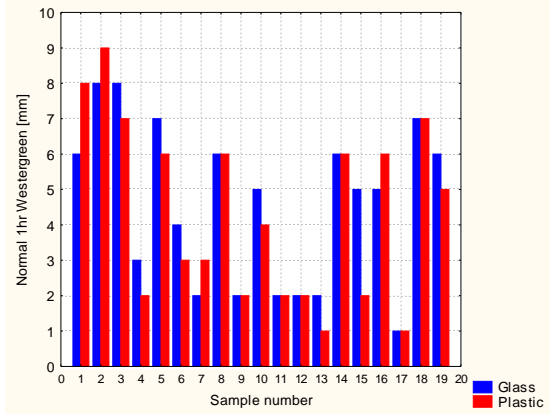
N = 21
P-value = 0,537
No statistical significance

Normal Donor Results

After 1h: female 1 – 11 mm/h, male 1 – 8 mm/h
 After 2h: female 6 – 20 mm/h, male 5 – 18 mm/h

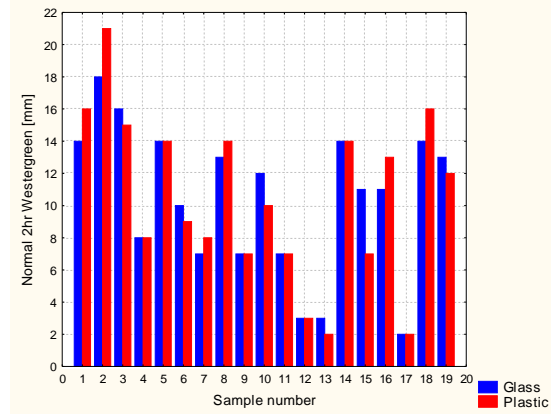
1 hour Westergren results

Bar Chart. Normal donor results at 1 hour Westergren for glass and plastic tubes [mm]:

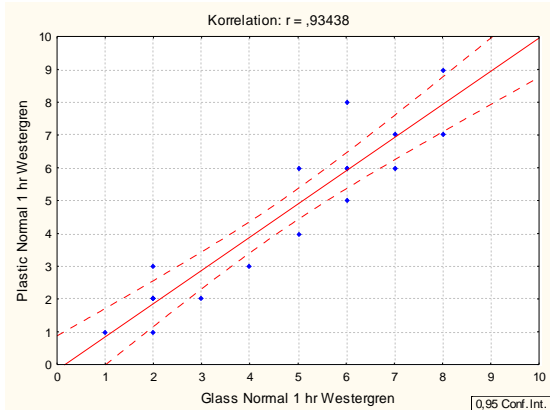


2 hours Westergren results

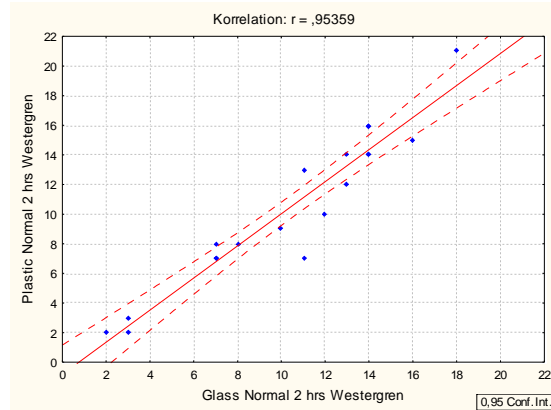
Bar Chart. Normal donor results at 2 hour Westergren for glass and plastic tubes [mm]:



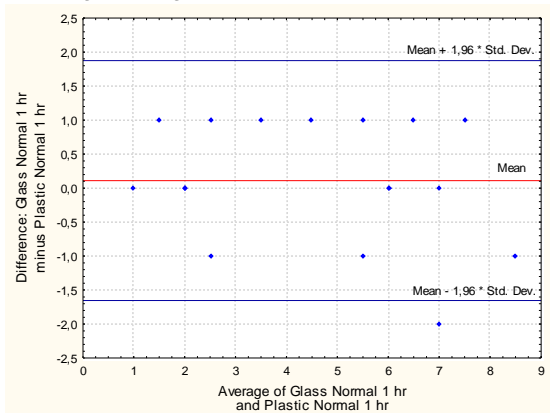
Regression Line. Normal donor results at 1 hour Westergren for glass and plastic tubes [mm]:



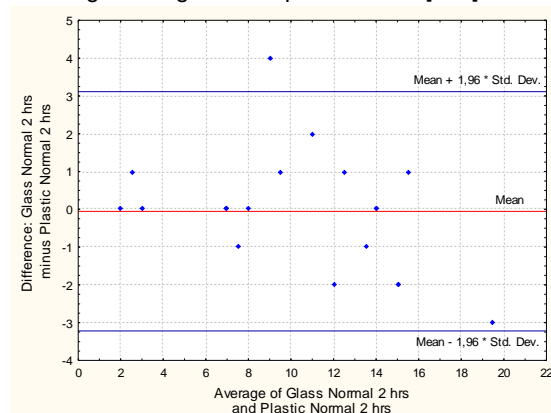
Regression Line. Normal donor results at 2 hour Westergren for glass and plastic tubes [mm]:



Bland-Altman plot. Normal donor results at 1 hour Westergren for glass and plastic tubes [mm]:



Bland-Altman plot. Normal donor results at 2 hour Westergren for glass and plastic tubes [mm]:



Paired T-Test at a significance level of 5%:

N = 18
 P-value = 0,607
 No statistical significance

Paired T-Test at a significance level of 5%:

N = 19
 P-value = 0,887
 No statistical significance