

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 from 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 on 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 66 healthy donors and 32 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. One hour and 2 hour Westergren values were determined with temperature correction at 18 °C. The analyses were 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:

Comparison analyses of **VACUETTE**[®] ESR glass tubes and **VACUETTE**[®] ESR plastic tubes was performed for 1 hour and 2 hour Westergren values.

Statistical evaluation was performed using StatSoft Software, Version 9. The found statistical differences may be neglected for clinical practice due to unspecific screening results and due to large intra-individual biological variations.

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 0.99171 and for the 2 hours Westergren 0.99500. The normal donor results showed a correlation of 0.93860 at 1 hour Westergren and 0.97219 at 2 hours Westergren.

Conclusion:

This test examined the performance of the **VACUETTE**[®] ESR plastic tubes in comparison with the **VACUETTE**[®] ESR glass tubes. On the basis of the data the **VACUETTE**[®] ESR plastic tubes can be used for the determination of Erythrocyte Sedimentation Rate, as no clinically relevant deviations between glass and plastic tubes could be found.

References:

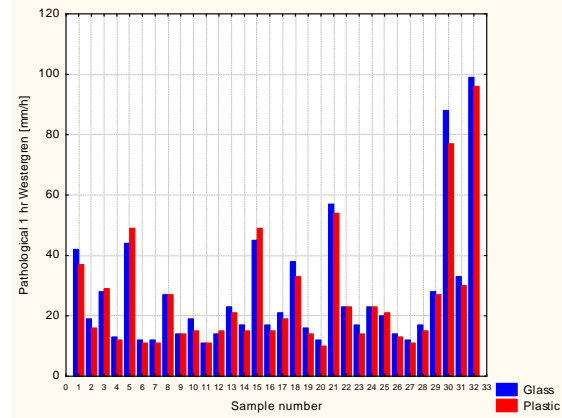
- [1] Koch, P. (2001). Comparison of Manual vs. Automated Blood Sedimentation Test: Quality and Economy. J Lab Med, 25 (5/6), 189-194.
- [2] Weiß, C. (2007). Basiswissen Medizinische Statistik (4. Aufl). Heidelberg: Springer.
- [3] Jou, J. (2011) ICSH review of the measurement of the erythrocyte sedimentation rate. Int. Jnl. Lab. Hem. 33, 125-132.

Results in detail

Pathological Donor Results

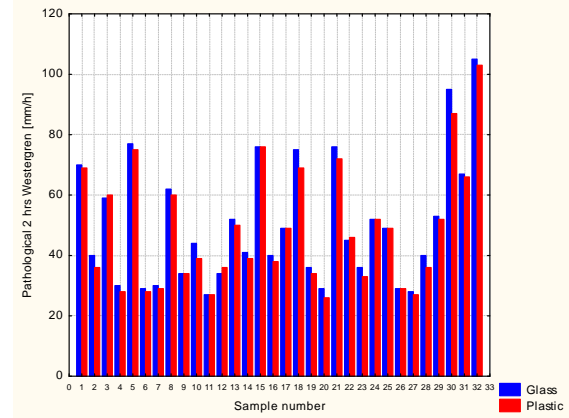
1 hour Westergren results

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

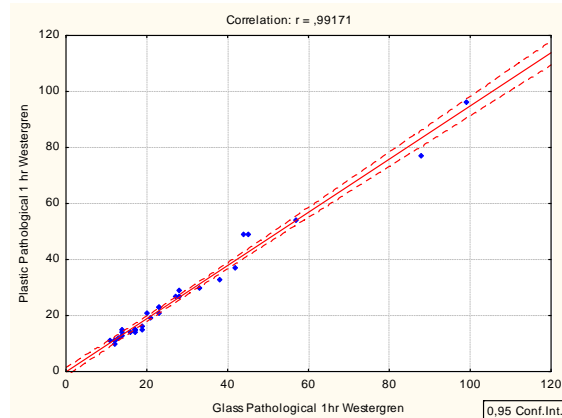


2 hours Westergren results

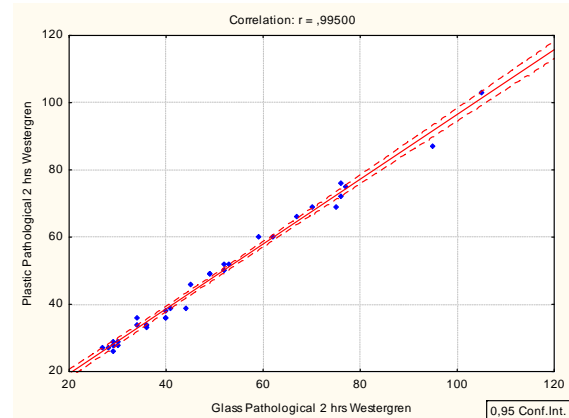
Bar Chart. Pathological donor results at 2 hour Westergren for glass and plastic tubes [mm]:



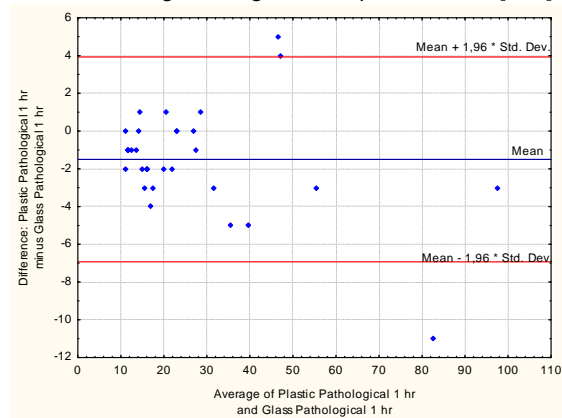
Regression Line. Pathological donor results at 1 hour Westergren for glass and plastic tubes [mm]:



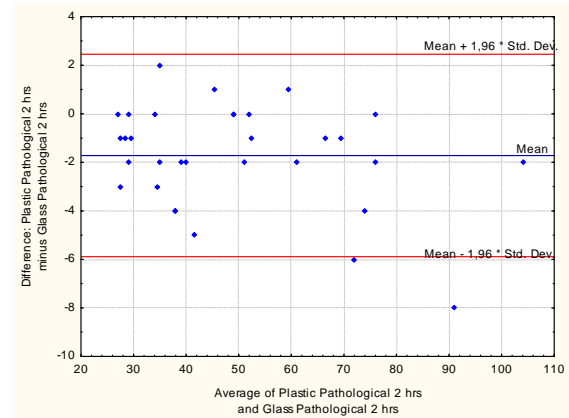
Regression Line. Pathological donor results at 2 hour Westergren for glass and plastic tubes [mm]:



Bland-Altman plot. Pathological donor results at 1 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 = 32
P-value < 0.001

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

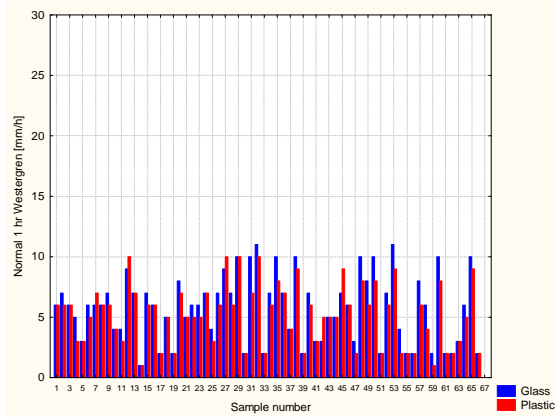
N = 32
P-value < 0.001

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

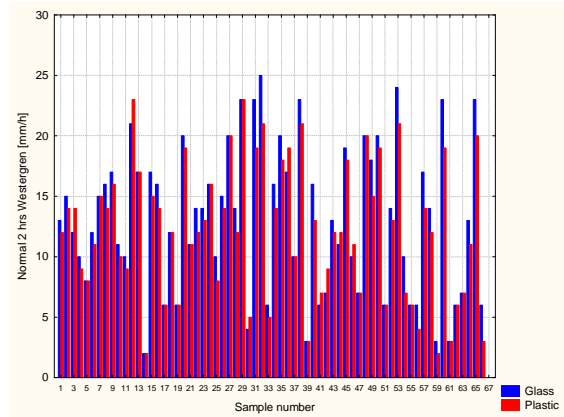
1 hour Westergren results

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

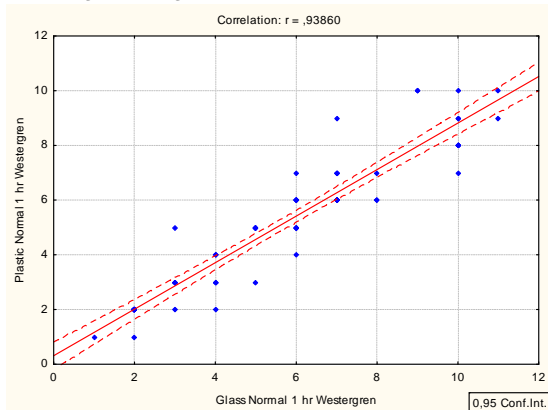


2 hours Westergren results

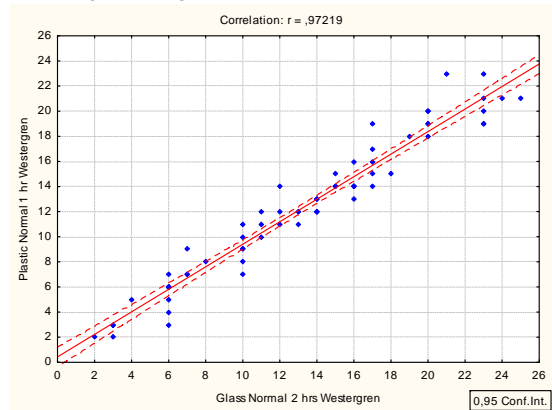
Bar Chart. Normal donor results at 2 hour Westergren for glass and plastic tubes [mm]:



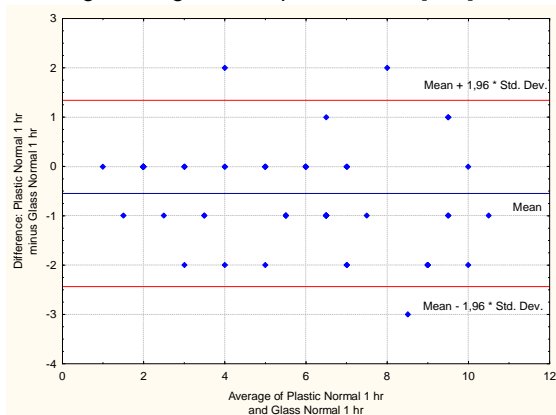
Regression Line. Normal donor results at 1 hour Westergren for glass and plastic tubes [mm]:



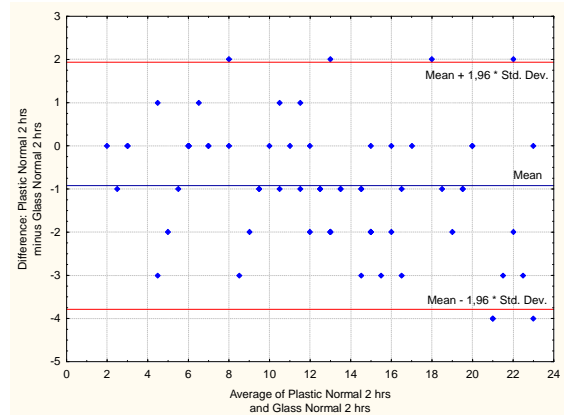
Regression Line. Normal donor results at 2 hour Westergren for glass and plastic tubes [mm]:



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 = 66
 P-value < 0.001

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

N = 66
 P-value < 0.001