

Evaluation of **VACUETTE**[®] Plastic ESR Tube with the manual closed ESR measurement

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 closed manual ESR measurement. The Erythrocyte Sedimentation Rate test measures the settling of erythrocytes in human plasma over a specified time. The closed manual ESR measurement delivers the 1 hour Westergren value after 60 minutes and the 2 hour Westergren value after 120 minutes. ^[1]

Study design:

The following tube types were used in this study:

- 9 x 120 mm 4 NC ESR Sod. Cit Glass with 2.9 ml draw volume (item # 729090)
- 9 x 120 mm 4 NC ESR Sod. Cit PP-Plastic with 2.75 ml draw volume (item # 729070)

Venous blood collection was carried out from 18 healthy donors and 27 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 (729090 and 729070), the order of draw was randomized. Directly after blood collection, the tubes were carefully inverted 8 times to allow proper mixing.

The Erythrocyte Sedimentation Rate performed by the Westergren method can be affected to an important degree by normal variations in room temperature. Therefore a nomogram for correlation to 18 °C for Westergren's method was used for values measured over the recommended room temperature (between 18 °C and 25 °C) ^[2]. The Greiner manual ESR measurement has a correlation of 0,996 to the Greiner automated ESR measurement ^[3].

1 hour and 2 hour Westergren values were determined by reading the distance (in millimeters) from the plasma meniscus to the top of the column of sedimented erythrocytes at 60 and 120 minutes immediately (max. 1 hour) after specimen collection. For the measurement, the Greiner ESR rack with a scaling was used (item # 836075).

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) was performed and showed that for the 1 hour and 2 hour normal donor results donor number 4 were outliers. For 1 hour pathological donor results donor number 24 was detected as an outlier. Therefore those donors were excluded from the statistical tests.

Paired T-test (α 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 with the closed manual ESR measurement.

Conclusion:

For the comparison of the **VACUETTE**[®] ESR glass tube and the **VACUETTE**[®] ESR plastic tube for the manual closed ESR measurement no statistical nor clinically significant differences were detected. The **VACUETTE**[®] ESR plastic tube is a suitable substitute for the current **VACUETTE**[®] ESR glass tube for the manual closed ESR measurement.

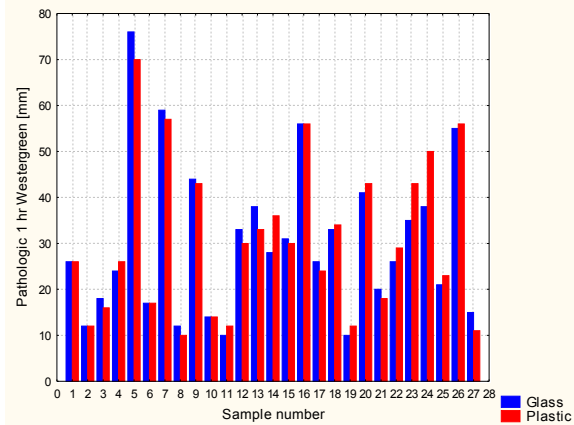
References:

- [1] CLSI (Clinical and Laboratory Standards Institute). Reference and Selected Procedure for the Erythrocyte Sedimentation Rate (ESR) Test; Approved Standard – Fourth Edition. H2-A4, Vol. 20 No. 27.
- [2] Manley, R. (1975). The effect of room temperature on erythrocyte sedimentation rate and its correlation. J. Clin. Path 10, 354, Department of Medicine, St. Stephen's Hospital, London.
- [3] Koch, P. (2001). Comparison of Manual vs. Automated Blood Sedimentation Test: Quality and Economy. J Lab Med. 25 (5/6), 189-194.

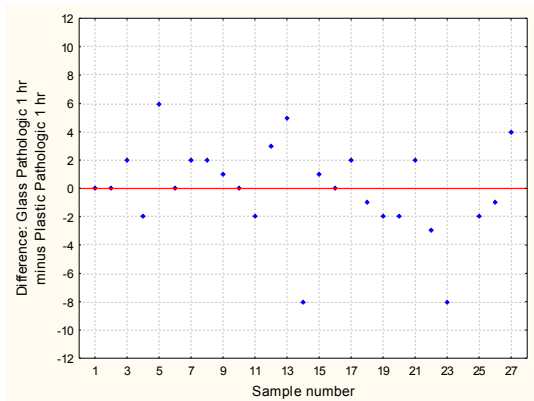
Results in detail – manual closed ESR measurement Pathological Donor Results

1 hour manual closed ESR measurement

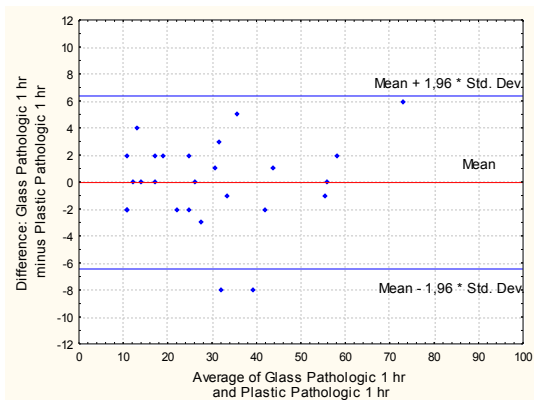
Bar Chart. Results from pathological donors at 1 hour for glass and plastic tubes [mm]:



Deviation Plot. Results from pathological donors at 1 hour for glass and plastic tubes [mm]:



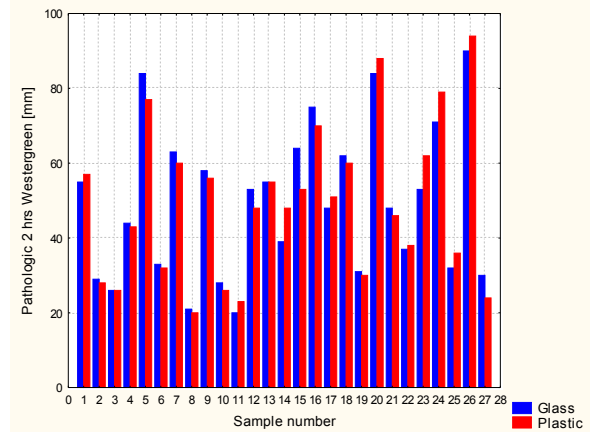
Bland-Altman plot. Results from pathological donors at 1 hour for glass and plastic tubes [mm]:



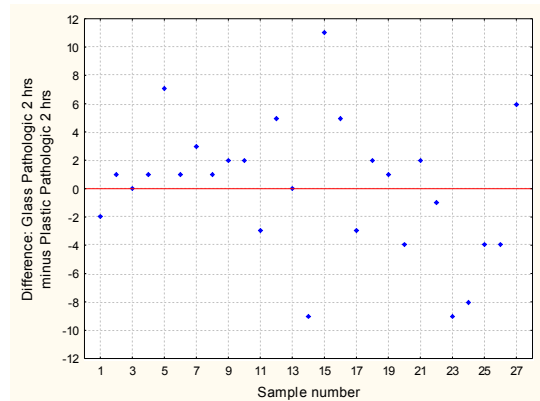
Paired T-test at a significance level of 5 % (outliers excluded):
 N = 26
 P-value = 0,952
 No statistical significance

2 hours manual closed ESR measurement

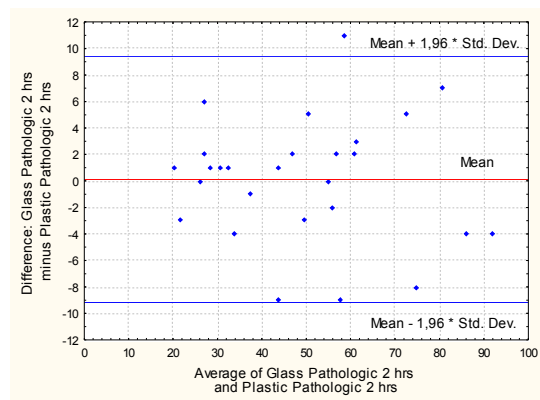
Bar Chart. Results from pathological donors at 2 hours for glass and plastic tubes [mm]:



Deviation Plot. Results from pathological donors at 2 hours for glass and plastic tubes [mm]:



Bland-Altman plot. Results from pathological donors at 2 hours for glass and plastic tubes [mm]:



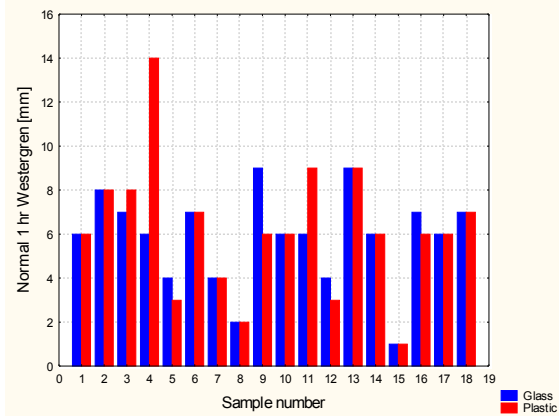
Paired T-test at a significance level of 5 %:
 N = 27
 P-value = 0,904
 No statistical significance

Normal Donor Results

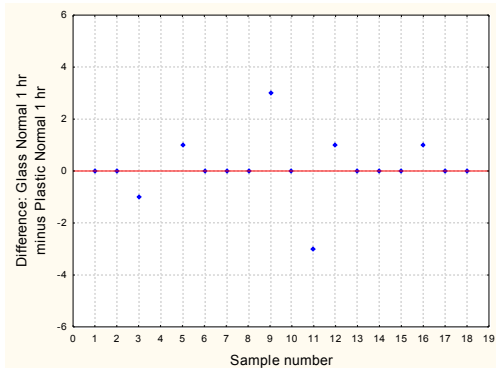
After 1h: female 1 – 11 mm/h, male 1 – 8 mm/h
 After 2h: female 6 – 20 mm/h, male 5 – 18 mm/h

1 hour manual closed ESR measurement

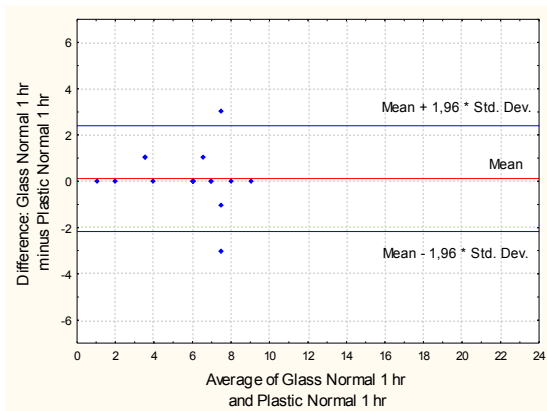
Bar Chart. Results from normal donors at 1 hour for glass and plastic tubes [mm]:



Deviation Plot. Results from normal donors at 1 hour for glass and plastic tubes [mm]:



Bland-Altman plot. Results from normal donors at 1 hour for glass and plastic tubes [mm]:



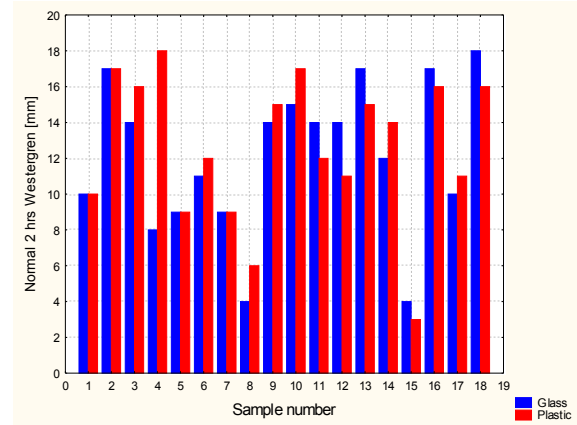
Paired T-test at a significance level of 5 % (outliers excluded):

N = 17
 P-value = 0,683
 No statistical significance

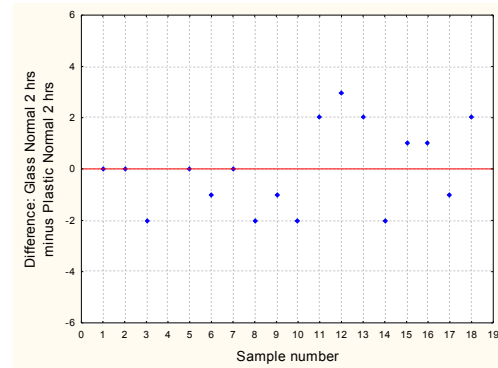
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2 hours manual closed ESR measurement

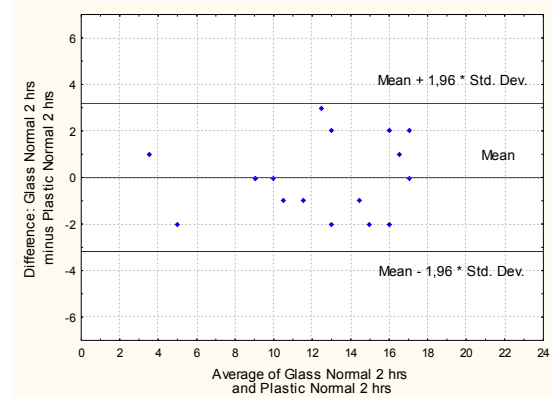
Bar Chart. Results from normal donors at 2 hours for glass and plastic tubes [mm]:



Deviation Plot. Results from normal donors at 2 hours for glass and plastic tubes [mm]:



Bland-Altman plot. Results from normal donors at 2 hours for glass and plastic tubes [mm]:



Paired T-test at a significance level of 5 % (outliers excluded):

N = 17
 P-value > 0,999
 No statistical significance