

S-Monovette® Hirudin

for the precise analysis of thrombocyte function



SARSTEDT

S-Monovette® Hirudin

Recombinant Hirudin is a direct thrombin inhibitor and very effectively inhibits blood coagulation (clotting), in vivo and in vitro. Hirudin as an anticoagulant has neither activating nor inhibiting influences on the thrombocytes and presents therefore as the “ideal” anticoagulant. Other anticoagulants have negative effects as is known from literature.

To determine the thrombocyte function so called aggregometers are used. One of the most used measuring tools for the thrombocyte function is the Multiplate system [1] from Dynabyte/ Verum Diagnostica. To calculate the thrombocyte aggregation with the Multiplate system it is recommended to use Hirudin-whole blood.

In 2008 Sarstedt AG & Co. in cooperation with Dynabyte was the first manufacturer to produce and launch a blood collection system with recombinant Hirudin as anticoagulant agent. The preparation of the S-Monovette® Hirudin was achieved with small plastic beads. Validation of the S-Monovette® Hirudin by Dynabyte showed overall a good correlation of the S-Monovette® with the manually produced Hirudin tubes from Dynabyte. In clinical applications, however, it appeared that the beads in some of the samples interacted stronger with the thrombocytes than was to be expected [2]. In line with our continual quality improvements, we applied an advanced production technique for the S-Monovette® Hirudin. During this involved process dry preparation is achieved without the use of plastic beads.

During validation the new S-Monovette® Hirudin was compared to the Hirudin tube of Dynabyte [3]. This was done internally by Sarstedt as well as externally by two independent institutions (Munich University Hospital, Department for Transfusion and Haemostasiology / Westpfalz-Klinikum Kaiserslautern, Medical Clinic III, Clinical Haemostasiology).

Correlation:

In order to determine correlation, blood collections with the new S-Monovette® Hirudin as well as with the Dynabyte Hirudin tube were performed in parallel. Then the samples were analyzed with the Multiplate system, and the results were correlated.

Fig. 1:

Performed tests: ADPtest, ASPItest, and TRAPtest
Number of performed analyses: 96

The correlation coefficient was 0.91.

Sarstedt AG & Co., Germany

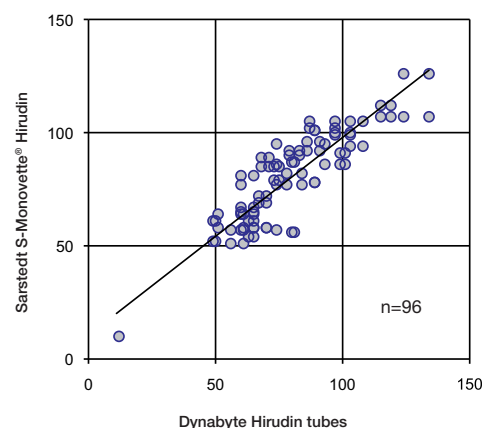


Fig. 2:

Performed tests: ADPtest, ADPtest HS, ASPItest, COLtest, RISTOtest, and TRAPtest
Number of performed analyses: 413

The correlation coefficient was 0.97.

Munich University Hospital, Germany, Department for Transfusion and Haemostasiology

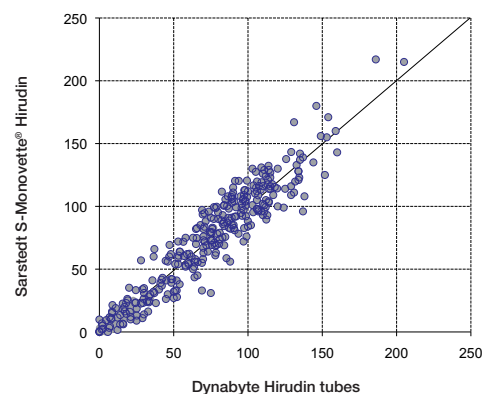


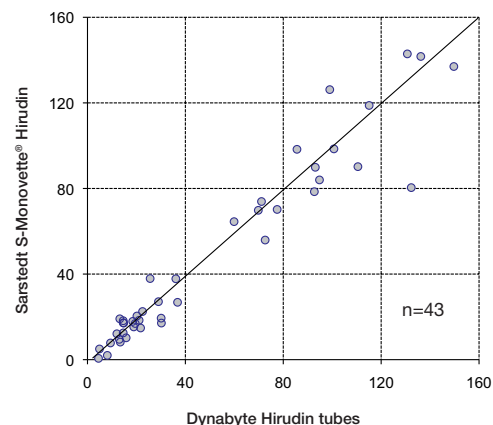
Fig. 3:

Performed tests: ADPtest, ADPtest HS, ASPtest, and TRAPtest

Number of performed analyses: 43

The correlation coefficient was 0.96.

*Westpfalz-Klinikum Kaiserslautern, Medical Clinic III,
Clinical Haemostasiology*



Absolute Aggregation:

In order to be able to state a value for the absolute aggregation, the medium values and standard deviations of the respective aggregation at Munich University Hospital were compared.

Fig. 4:

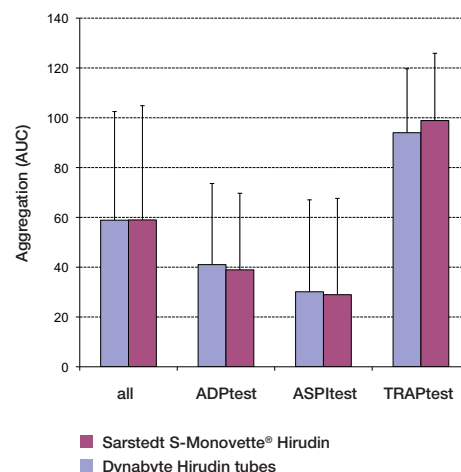
Number of performed analyses: 413

Number of performed analyses, ADPtest : 115

Number of performed analyses, ASPtest : 113

Number of performed analyses, TRAPtest: 110

In addition to very good correlations, the measured absolute aggregations also correlated very well.

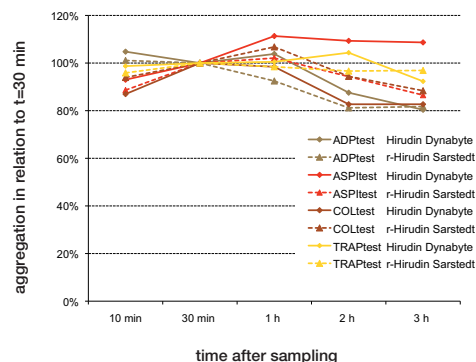


Stability of samples:

Stability was compared between the manually produced Dynabyte Hirudin tubes and the new Sarstedt S-Monovette® Hirudin.

Fig. 5:

As shown in the graph, the aggregation diminishes by approx. 20% during a three hour period without any significant difference between the two tubes in regards to diminishing activity.

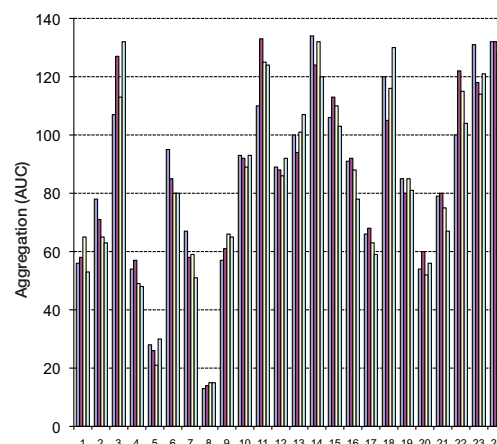


Reproducibility:

In total 24 four-time measurements in series were performed using the reagents ADPtest, ASPItest, COLtest and TRAPtest.

Fig. 6:

Overall a median variation coefficient of 7.1% was observed which is within the expected parameters for the Multiplate analysis (typical medium v-c 6-8%)



Summary

The new Sarstedt S-Monovette® Hirudin performs equivalently to the manually produced Hirudin tubes from Dynabyte. All test results showed very good correlation and the deviations found were due to variations in the reproduction of the process. When compared to the first generation of the S-Monovette® Hirudin (with plastic beads, Art. No. 04.1912.001) there was a better correlation of the measured aggregation with the Hirudin Tubes from Dynabyte (no picture).

Currently only S-Monovette® Hirudin without plastic beads are available. The first generation of the S-Monovette® Hirudin with plastic beads has been discontinued. In addition, the Dynabyte Hirudin tubes will no longer be offered. This standardization has considerable advantages for the application of the Multiplate process. Among other things, it will be easier to compare experiences and outcomes between different institutions and those will be easier to share.

Literature

1. Whole blood analysis to determine primary haemostasis, Andreas Calatzis, J Lab Med 2007; 31 (6):239-247
2. Effect of the Blood Collection Tube on Multiplate Analysis in Hirudin Blood: Sarstedt S-Monovette® r-Hirudin and Vacuplus Hirudin, report, Andreas Calatzis, Michael Spannagl
3. Comparison of Two Different Blood Sample Tubes for Platelet Function Analysis with the Multiplate® System, Ralph Loreth & Gudrun Klose, Westpfalz-Klinikum GmbH Kaiserslautern, Transfus Med Hemother 2010;37 (5): 289-292

Ordering Information

| Order No. | Description | Packaging |
|-------------|-----------------------------|------------------------------|
| 04.1944.001 | S-Monovette® Hirudin 2,7 ml | 50 / inner box 500 / case |

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