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Technical Bulletin – Helena AggRAM™ Platelet Aggregation System

Executive Summary

AggRAM™ and Helena Aggregation Reagents have been chosen by laboratories worldwide for more than three decades. Through this history of providing light transmission aggregometry (LTA), an anomaly has been noted on a few occasions where the aggregation trace exhibits a sharp drop followed by a "noisier" trace such as that in Figure 1 or exhibits a noisy trace such as that exhibited in Figure 2.

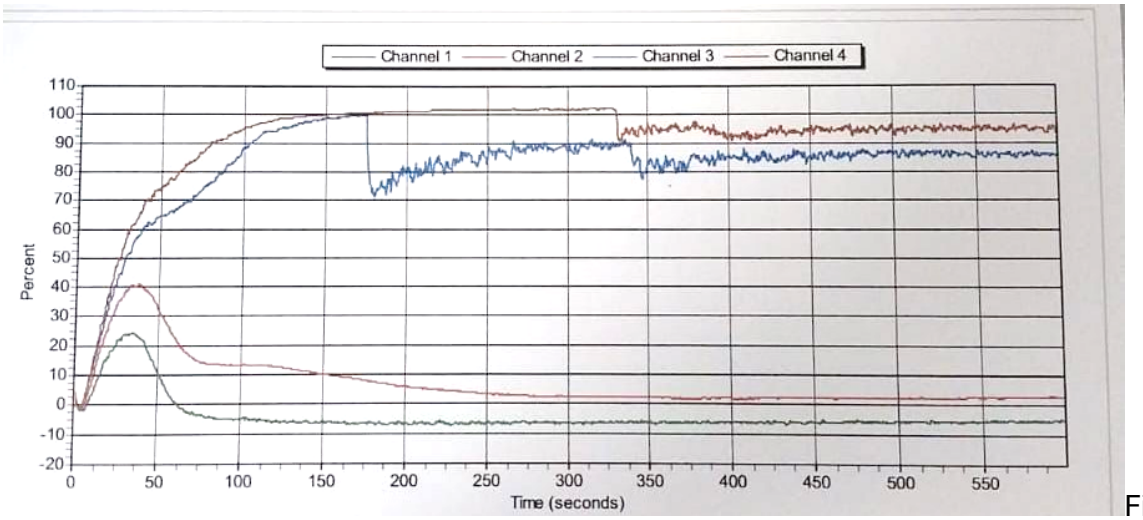


Figure 1. AggRAM traces showing drop in % aggregation followed by noisier trace.

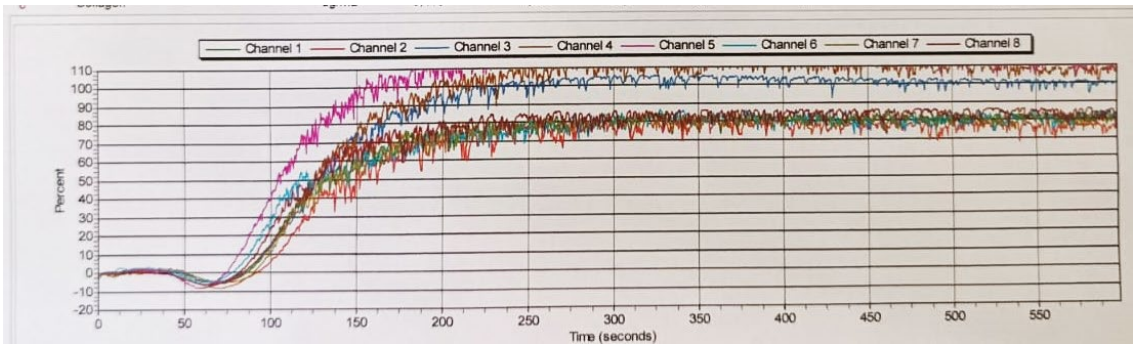


Figure 2. AggRAM traces showing noisier traces throughout a run.

Helena has been unable to reproduce these "noisy" traces despite investing many hours in engineering experiments focused on the hardware and software as well as scrutiny of reagents. Examination of historic records from internal testing only produced evidence from one result.

Discussion and Conclusion

During LTA, platelet agonists trigger platelet aggregation/agglutination, and in that process platelet receptors become biologically available or "sticky". As the thrombus develops, the outer unbound portion can bind to additional platelets or surfaces that have adsorbed protein such as the stir bar or the reaction cuvette. Such adsorption is highly likely to occur if their respective surfaces are damaged by reuse/cleaning or as the result of a manufacturing defect.

LTA is measured by detecting the amount of light that passes through the cuvette as the thrombus develops. If the thrombus attaches to the magnet or if the thrombus fissures over time, the trace can drop and become noisy and then "recover", in some cases, with the trace returning to a more expected curve. In addition, if the surface treatment of the cuvette is damaged allowing exposure of bare glass, proteins and/or thrombus can adhere blocking light transmission, partially causing a permanent reduction in light transmission or correcting over time (but often exhibiting a noisier trace). Noting maximum aggregation is imperative in determining the efficacy of the results.

Fluctuating electrical power to the AggRAM can also result in noisy traces. Helena recommends use of an appropriate Uninterruptible Power Supply (UPS) if "clean power" is in question.

We have consulted with numerous outside experts aside from the rigorous in-house testing outlined earlier and have concluded that results described above should not be considered diagnostic in terms of platelet pathology. We suggest end users contact Helena Technical Services staff any time there is concern, and we emphasize the following:

- Always repeat questionable results. If contacting Helena for support, please gather information like lot number of reagents, serial number of the AggRAM system, relevant patient information (if potentially a factor) and copies of traces.
- Never reuse cuvettes. Cleaning of the glass can cause damage to the surface treatment and any residual proteins or platelet left behind can cause inaccurate or poor results.
- While stir bars are disposable, they can be reused only if these conditions are met:
    - Stir bars must be cleaned chemically with detergent/surfactant only. Abrasive materials can cause surface damage.
    - If damage or oxidation is observed OR the lifespan specified by the institution has expired, the stir bars must be replaced.

For more information, contact Technical Services by calling 409-842-3714 or 800-231-5663 (USA) or by email at technicalservice@helena.com.

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