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Coagulation testing in the context of the automated hospital lab and optimizing for the effects of common interferences

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Coagulation testing is central to diagnosis of patients with hemostasis disorders and is critical for monitoring of antithrombotic therapies. Despite this, there is a lack of clarity in the published literature on the impact of hemolysis on the measurement of PT/aPTT using automated coagulation measurement instrumentation.

Objective: To evaluate the impact of hemolysis on the accuracy of the standard coagulation tests PT and aPTT in patients not undergoing anticoagulation therapy and in patients undergoing heparin therapy.

Methodology: Na-citrate plasmas were obtained from an emergency room setting and processed within 2 hours of collection. Two patient populations were collected 1) 60 patients excluding those undergoing anticoagulation therapy; 2) 20 patients actively undergoing heparin therapy. For both populations, samples were divided and one aliquot was lysed mechanically by drawing through a 25 gauge needle. Both aliquots were then separated in a Hettich centrifuge and for each paired sample the degree of hemolysis was measured as a plasma index on the Roche Modular DPP and the coagulation measurements PT/aPTT were determined on the Diagnostica Stago STA-R Evolution®.

Results: Mechanical shearing of samples by passage through a 25 gauge syringe produced significant hemolysis, as 87% of samples had plasma indices less than 10 prior to hemolysis, compared with 87% having indices greater than 20 following hemolysis. In comparing mean PT and aPTT values in normal vs hemolyzed samples we observed no significant difference for either value ($p = 0.67$ PT; $p=0.65$ aPTT) for the patients not undergoing anti-coagulation treatment. While not statistically significant, we observed a trend to decreasing values for the aPTT in the hemolyzed samples. To establish performance parameters, we applied acceptable biological variation values (PT=5.3%, aPTT=4.5%) and compared the frequency of ΔPT and aPTT results pre and post hemolysis. By this analysis, 100% of the PT values fell within the acceptable range regardless of the hemolysis index, whereas for aPTT, 21% of samples exceeded the acceptable variation cutoff. Employing a hemolysis Index cutoff of less than 313, 75% of samples were tested and of these 95% fell within the acceptable variation. In preliminary analysis of the data, we observed an apparent interference in the aPTT test with heparin therapy and the degree of hemolysis. We examined this in further detail in a collection of 20 patients on heparin therapy. In comparing the aPTT data between the heparin treated and the non-coagulation results we observed the expected increased aPTT time. However, within the heparin therapy group, 19 of 20 samples (95%) had a ΔaPTT value outside the acceptable variation range (4.5%), compared with only 21% in the non coagulation group.

Conclusions: The data in this study demonstrate that in establishing an automated coagulation analysis workflow, it is essential to include characterization of the potential interference of hemolysis with the aPTT assay, whereas the PT assay appears to be more robust with respect to hemolysis. Furthermore, where samples are likely to include heparin treated patients, characterization of the effect of hemolysis is essential since 95% of samples exceeded the acceptable biological variation.