Stago
USA

TO WHOM IT MAY CONCERN,

This letter addresses the issue of the 0.85 slope adjustment factor applied to APTT's run on all Diagnostica Stago instrument systems in the United States.

Background:
In 1995, the STA coagulation analyzer was launched in the United States. The predicate device for the STA was the Stago ST4—both implement an identical method of viscosity based, mechanical clot detection. The issue of correlation to a back-up analyzer that used a different method of clot detection, was an immediate competitive challenge. Early evaluation statistics suggested that the STA APTT results were consistently longer than results from the photo-optical competitor instruments (back-up analyzers). Since our customers required standardized reference and therapeutic ranges for both primary (i.e. STA) and back-up analyzers (i.e. MLA, X2, ACL, CA series) we instigated a multi-center study to help identify an appropriate slope adjustment factor that when applied to the STA system would allow standardization of results. The information obtained from this comprehensive study suggested that the difference in APTT values was a result of methodological slope adjustment of 0.85. When this adjustment was applied to the APTT on the STA the corrected difference yielded acceptable correlation values between the STA and any photo-optical type back-up analyzer that the customer would have. Subsequently, method validation and correlation studies at each installation site have shown the full family of Stago analyzers (STA, STA-Compact, STA-R, STA Compact CT, ST4 and STArt 4/8) to respect the 0.85 slope adjustment when compared to photo-optical systems of clot detection.

Example: STA APTT result X 0.85 = photo-optical APTT result.

The 0.85 factor was /is applied to the automated systems via Test Set-up for APTT.

The 0.85 factor can be applied manually to the raw ST4 and STArt 4/8 APTT patient results in order to make them match the patient APTT results generated on the automated STA systems.

In summary, the 0.85 slope adjustment factor was developed and is still in use today because of the following:

1. We had no automated back-up analyzer at the time of the STA launch. Standardization of results and competitive pressure forced us to come up with a solution.

2. Since the adjustment was applied at launch, CAP survey data was immediately affected. It is now impossible to remove it.

Sincerely,

Daniel A Kaczor, MT(ASCP)
Director, Technical Service Department