Biological variation and quality control

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Monitoring of test imprecision is one of the most important quality indicators in clinical laboratories. The analytical imprecision that is acceptable for a diagnostic test can be determined based on the biological variation of the variables, which is the natural within-subject variation over time. Data from biological variation studies can be used to define desirable goals for imprecision, bias and total error, indices of individuality and reference change values.
Also the plasma concentrations of hemostatic variables are influenced by biological variation. During this presentation, an overview of the available data on biological variation in hemostasis factors and its effects on analytical imprecision are presented. Detail will be presented of a study that we performed in the Netherlands: In longitudinally collected samples (520 blood samples over a 1-year period from 40 healthy individuals) the biological and seasonal variation of hemostasis variables were determined, including fibrinogen, platelet aggregation, thrombin generation, prothrombin time (PT), Von Willebrand Factor, fibrinolysis, C-reactive protein and the coagulation inhibitors antithrombin, protein C and Protein S. We calculated the recommended analytical imprecision for diagnosis and monitoring; the recommended analytical bias; the contribution of analytical imprecision to test result variability; the index of individuality; the reference change value; and the number of repeated measurements needed to obtain the true habitual concentration of an individual. In addition, the sources of biological variation were further studied by determining the seasonal variation, the effect on inflammation, gender, blood group (for VWF) and particulate matter.
In conclusion, biological variability of hemostatic markers is a valuable tool to determine the analytical quality specifications.