# Validation of the Sysmex CS-5100 coagulation analyzer for routine hemostasis parameters

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The Sysmex CS-5100 is a fully automated coagulation analyzer performing coagulation and chromogenic and immulogic hemostasis assays using multiple wavelength technology. Two Sysmex CS-5100 systems were validated for the determination of routine coagulation parameters at the University Hospital of Antwerp (UZA), where they are replacing the STA-R Evolution® systems (Stago). Two major advantages over the STA-R Evolution are the sample volume check and a scan for hemolysis, icterus and lipemia that are performed by Sysmex CS-5100 to identify potential preanalytical inaccuracies. Following parameters were assessed in the validation: activated partial thromboplastin time - APTT (Dade Actin FS), prothrombin time - PT (Dade Innovin), fibrinogen (Dade Thrombin) (all coagulation assays), D-dimers (Innovance D-dimer, immunologic assay), and antithrombin (Innovance Antithrombin, chromogenic assay).

Validation and verification of reference intervals were performed in accordance to CLSI guidelines (H57-A, H47-A2 and C28-A3). The within-day and between-day precision were below the manufacturers' criteria for all parameters. The accuracy and total error did meet the criteria of Ricos (minimal criteria for bias and total error), except for antithrombin at a pathological concentration. For the APTT, the calculated reference range was different from the reference range given by the manufacturer; for the PT, fibrinogen, D-dimer and antithrombin, the reference range of the manufacturer could be used.
A comparison study with the STA-R Evolution was performed. Since different reagents and a different detection method were used, significant differences were observed between the two analyzers. The most prominent difference was observed for the APTT.
Since the APTT is used for monitoring unfractionated heparin therapy, the therapeutic APTT range needed to be established "in house". In our settings the therapeutic anti-Xa range of 0.3-0.7 IU/mL corresponded with an APTT range of 60-90s when using the Dade Actin FS reagent.
The sensitivity of the APPT and PT reagents towards factor deficiencies was evaluated (FVIII, IX, XI and XII for the APTT and FII, V, VII and X for the PT). The APTT reagent showed factor sensitivities between 46-72% for the different factors, while the PT reagent showed factor sensivities between 34-52%.
After validation and before implementing the Sysmex CS-5100 systems in routine extensive information about the consequences in daily practice was provided to the physicians in multiple newsletters.

In conclusion the CS5100 instrument is suitable for the determination of the APTT, PT, fibrinogen, D-dimer and antithrombin for routine analysis.