Pre-acquisition system assessment of the Sysmex® Coagulation System CS-2100i and comparison with end-user verification; a model for the regional or national introduction of new analyzers and methods.

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Introduction: Pre-acquisition system assessments of clinical laboratory analyzers and/or methods are generally repeated independently in each individual organisation planning their introduction. In the course of replacing our 10-year old Sysmex® CA1500 for CS2100i coagulometers, we designed and tested a model in collaboration with Siemens Healthcare Diagnostics based on CLSI protocols in which one laboratory performs a so-called super-user validation, allowing others to rely on a concise verification only.

Design and methods: Validation of the Sysmex® CS-2100i was performed largely according to Clinical and Laboratory Standards Institute (CLSI, Wayne, USA) Guideline H57-A (Protocol for the Evaluation, Validation, and Implementation of Coagulometers, 2008) and included EP-5, 7, 9 and 10 protocols in the evaluation of 10 assays encompassing all measurement principles available. EP-15 was used for the end-user verification. Practicability and results of validation and verification were compared.

Results: The analytical performance of the CS-2100i was as claimed by the manufacturer and complied with our own (often more strict) criteria for all assays. Results of the system verification had sufficient statistical power and were compatible with those of the super-user validation. Verification was very time effective.
(completed in 3 weeks against 3 months for the validation), and its reagent costs were estimated to be approximately 5 times lower.

Conclusion: We have approved the Sysmex® CS-2100i analyzer for introduction in our laboratory. For other buyers a system verification is proposed to be sufficient when referring to our data, and restricted to the 10 assays studied. It is our intention to use the super-user validation versus end-user verification model for future method introductions and when harmonising between our different locations.