

## ABSTRACT FORM ECAT SYMPOSIUM 8 – 9 NOVEMBER 2018

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### Title:

**Autovalidation of coagulation test results**

### Abstract:

To date, significant efforts have been made in the automation of the preanalytical and analytical phases. However, as the postanalytical phase still relies mostly on manual review and validation of test results, autovalidation has been proposed as a possible solution for the automation of the postanalytical phase. Autovalidation is an algorithm-based process for the validation of test results that performs results checking according to established and verified criteria. The prerequisite for the implementation of autovalidation is to design a comprehensive autovalidation algorithm comprised of a set of autovalidation rules needed to achieve the optimal output and quality of autovalidated results.

The majority of published autoverification/autovalidation data are in the field of general clinical chemistry and hematology. Data regarding autovalidation of coagulation test results are scarce and the lack of clear-cut rules which could be used in the autoverification of test results has been suggested as a potential explanation.

For the implementation of autovalidation of coagulation test results two main important components are needed: modern coagulation analyzers with the ability to perform automated rerun and reflex testing according to instructions defined in the analyzer software and the laboratory information system (LIS) with the ability to send all test orders to the analyzer, autovalidate test results according to predetermined criteria and send them to the hospital information system.

Although coagulation analyzer manufacturers usually predefine a number of rerun and reflex testing instructions within the software, laboratories willing to implement autovalidation have to define their additional laboratory-specific instructions in order to achieve the highest possible rate of automation. Furthermore automatic release of specific results that will be transferred to the LIS can be configured at the analyzer level with the option of releasing valid results only, valid and doubtful results (results with generated analyzer flags) or all results including invalid results.

Among a variety of LIS-based autovalidation rules proposed in the literature, autovalidation range and delta check criteria are always included. Autovalidation range is a range of values that can be reported automatically for a specific test, whereas delta check criteria are used to detect changes in the patient's conditions by comparing a patient's current result with the previous one in a defined time frame. Delta check criteria can be defined in different forms and therefore it has been suggested that every laboratory should define their own criteria for each single test including the delta check time period in days.

The purpose of the autovalidation algorithm is to enable that only results that met all defined criteria are autovalidated, whereas in case when any of the criteria is not fulfilled, autovalidation of test results is stopped in the LIS for manual validation. Finally, in order to check the functionality of the autovalidation algorithm before the implementation in routine practice, it has to be verified according to the approved Clinical and Laboratory Standards Institute guideline for autoverification of clinical laboratory test results Auto10-A.

Obtained autovalidation rates show great variations depending on the setting and implemented autovalidation criteria, resulting in lower rates if both in- and outpatients are included compared to that when only outpatients are included. Undoubtedly, all published studies proved that autovalidation of coagulation test results reduce the number of manually validated test results and turnaround time for selected coagulation analyses, improving at the same time laboratory work efficacy.

In conclusion it has to be pointed that autovalidation can be relatively easily implemented in any coagulation laboratory by using "custom- made" autovalidation criteria tailored to the specific clinicians and laboratory needs.