ABSTRACT

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Title of diploma thesis: Optimization of a new analytical system for selected biochemical and immunochemical methods

Specific requirements for validation and verification of analytical methods according to the ČSN EN ISO 15189: 2013 standard must be met by every medical laboratory. The aim of the work was to meet the requirements of verification in the introduction of a new analytical system Cobas 8000 and also to compare the results with those obtained using older analyzer Cobas 6000 in the laboratory of clinical biochemistry.

For the analysis of biochemical and immunochemical methods, we used diagnostic kits from the same supplier Roche s.r.o. We determined the selected clinic-biochemical markers by the basic methods using spectrophotometry, immunoturbidimetry and electrochemiluminiscence. We used certified calibration and control material in the process of method verification. The mixed patient serum was used for the evaluation of repeatability and comparability of the methods.

We evaluated the verification and repeatability of methods using Microsoft Excel software. We compared the resulting measurement uncertainties and coefficients of intermediate precision with the maximum values of acceptable differences from the documentation of the external quality assessment from the company SEKK s.r.o. for 2022. To compare 9 selected methods, we used statistical tools regression analysis according to Passing-Bablok and a difference graph according to Bland-Altman.

The results of verification, repeatability, and comparability of selected methods for both automatic analyzers met our requirements for the intended use in clinical practice.

Keywords: validation, verification, uncertainty of measurement, intermediate precision, repeatability, comparability