QUALITY OF BIOCHEMICAL STUDIES USING VALIDATED PROCEDURES IN CLINICAL DIAGNOSTICS LABORATORY OF THE CLINICAL DIAGNOSTIC CENTER OF THE NATIONAL UNIVERSITY OF PHARMACY

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Introduction. The main strategic direction of modern laboratory diagnostics development is to create a quality management system, constant improvement of the clinical laboratory tests quality. Quality in laboratory diagnostics understand means the presence of confidence that is designed to timely patient test performed at a sufficient analytical level and accompanied by the necessary information for its interpretation.

One of the stages of development and implementation of quality system is validation work, which is confirmed by research and provide objective evidence that the particular requirements for a specific target application run. The main object of evaluation are methods used to conduct the measurement of various parameters in the laboratory, and in order to guarantee reliable and accurate analysis, a procedure for validation of laboratory methods.

Aim. The aim was to study the factors of quality assurance in Laboratory of Clinical Diagnostics of Clinical Diagnostic Center of the National University of Pharmacy through the validation work to assess the suitability of biochemical methods and determine the features, approaches and requirements to assess the suitability (validation) laboratory techniques and key moments of uncertainty.

Materials and methods. At the Laboratory of Clinical diagnostics validation methods were conducted: "Comparison of the quality and reliability of determining the level of total cholesterol in biological liquids by photometric method using biochemical analyzer Express Plus" and "Comparison of the quality and reliability of determining the level of triglycerides in biological liquids by photometric method using biochemical analyzer Express Plus".

These biochemical techniques that characterize lipid profile, can objectively assess the disturbances in lipids metabolism. Deviation in indicators of lipidogram of their reference values indicates the likelihood of a human atherosclerosis, liver and gallbladder diseases, as well as to predict the risk of these pathologies.

In our work we used analytical, statistical and biological methods.

First of all, the validation script was compiled: set data features of methods; analyzed the parameters to evaluate. Then we developed a validation protocol which

defines the personnel involved in the validation procedure under development; provides information on the proper functioning of equipment used; established a list of tests (methods), conducted during the validation and selection is made suitable for assessing the statistical methods of processing measurement results.

Researches were conducted using on standard samples with known concentrations of investigated analytes using automatic biochemical analyzer Express Plus. Over the methods validated characteristics were determined: specificity, and reproducibility of convergence, correctness of methods, uncertainty of measurements.

In assessing convergence and reproducibility of an analysis of the possible causes loss of accuracy in the determination of biochemical parameters. The main source of loss of precision when working on the device is operator-technician that performs research. From his skills and skill levels depends on the accuracy and reliability of measurements validation conducted.

To test the impact factor "assistant operator" for convergence and reproducibility within the laboratory two equal laboratory operator-training measurements conducted five observations on standard specimens total cholesterol (C = 7.55 U/l) and triglycerides (C = 2.02 U/l). Based on these data it was concluded that the homogeneity of variances and that the sample belonging to the same general population. Thus, these techniques are intra-laboratory test on the convergence factor.

The next step was conducted correctness of methods, which evaluated using standard samples in the laboratory. Subject to the requirements of the State Pharmacopoeia of Ukraine held in each series of five measurements. The study found that conducting all measurements with the same accuracy (convergence measurements) and confirmed the correctness of methods at different times of Biochemical analyzer Express Plus.

It was also calculated the expanded measurement uncertainty in terms of convergence, reproducibility and accuracy of this technique as metrological evaluation date. Expanded uncertainty showed that the values of total cholesterol and triglycerides can be considered accurate and reliable result indicates no gross errors in the analyzer and statistically significant differences in the measurements, laboratory operators.

The results and conclusions. Validation of methods for determining of total cholesterol and triglycerides in biological liquids the during work on the biochemical analyzer Express Plus in the Laboratory of Clinical Diagnostics of Clinical Diagnostic Center of the National University of Pharmacy proved that these methods have performance meet regulated, meet the established criteria, and measured them using the proper match.