Analytical Approach for vacuum tube validation: Comparison procedure of blood collection tubes as a part of local validation in pre-analytical phase

Svetlana Kovalevskaya[1], Lina Khorovskaya[2], Inna Schmidt[3], Anders Kallner[4]

[1]First Pavlov State Medical University, Saint-Petersburg, [2]North-Western State Medical University, Saint-Petersburg
[3]St. Luka Hospital, Saint-Petersburg, Russia, [4]Kalorinsla Hospital, Stockholm, Sweden

Background: Validation and verification of blood collection tubes became procedures that medical laboratories need since they are using different brands of IVD technologies for preanalytical phase. Common principles of comparisons of tested and reference tubes from analytical point of view are explained with evaluation of precision from duplicates, trueness, and ordinal linear regression analysis with indication of risk in clinical interpretation, estimation of difference and normality of distribution.

Objectives: To apply analytical validation approach for different brands of tubes with clot activator by method describes in CLSI protocols EP9-A. EXCELL spreadsheet program developed by Kallner A. are used for calculation quality specification, regression analysis and visualization graphs of comparisons

Methods: Sample collections were made in 40 patients from St. Luka Hospital to two tubes of Lind-Vac (Estonia) and Vacuette (Austria) per each using CLSI H3-A6 and analyzed in biochemistry analyzer RX Imola Randox (Ireland) on 13 analytes: AST, ALT, ALP, Amy, Total Calcium, CK, Cre, Iron, Total Protein, Triglycerides, T. Bil, Urea, Uric Acid.
Independent variables assume to be the results of measurements received from a reference Vacuette (Austria) or control tube and are plotted on the X-axis. Depended variables are received from comparative or tested tube Lind-Vac (Estonia) and take up position on Y-axis. Comparison procedure assumes that there is no measurement uncertainty in the independent variable therefore use of the ordinary lest square regression (OLR) seems one of the most acceptable practical approaches for this purpose. Error grid estimated patient risk depending on Allowable Total Error (ATE) that is equivalent to Total Error (TE). ATE assumes allowable variability that leads to correct test interpretation and has a status of A-Zone. C-zone indicates a risk for patient.

Results: Results of comparisons of tubes with clot activator (tubes with red cup) did not revealed any significant difference between samples from Lind-Vac and Vacuette tubes ($p>0,05$). Imprecision from duplicated (CV%) significantly differed on the results of 7 analytes for tubes with clot activator and clot activator and gel ($p<0,05$). Nevertheless values of CV% were in frame of international quality goals based on biological variation for imprecision and had no any influence to test interpretation. Ordinary linear regression graph demonstrates results with slope 0,96±0,01 and intercept 0,81±0,51. 95,8 % of the observations are within zone A (±14,6 % ATE) from the OLR and 14,2 % fall in the B-Zone and no results are found in the C-zone.

Conclusions: Implementation of CLSI protocols for complex analytical validation of evacuated tubes optimizes harmonization and standardization of verification and validation procedures of preanalytical phase of the laboratory process. Spreadsheet program in Excel simplifies analytical validation of blood collection tubes and could be used in routine laboratories.