Laboratory management, accreditation in laboratory medicine

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EVALUATION BUDGET FOR THE MEASUREMENT UNCERTAINTY OF ALANIN AMINOTRANSFERASE IN SERUM

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BACKGROUND-AIM

Doctors and patients are expecting high-quality laboratory results. Although all measurements are affected by a certain error it is very important to know what size the measurement error might be. The measurement uncertainty (MU) could be a solution. MU is defined as a non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand. Estimating and reporting the UM is required of laboratories accredited to ISO/IEC 17025 and ISO/IEC 15189, but there are many papers about the method performance data in evaluation MU. Faced with these requirements our laboratory had to choose a guide. The aim of this study was to demonstrate MU evaluation of serum alanine aminotransferase (ALT) using the top-down approach with a main goal to improve the quality of the test.

METHODS

Material: Chemwell automatic biochemical analyzer (Awareness Technology, Inc.) was used. Reagents and control materials were from Human Diagnostics. Evaluation method included: description of the measurand, study of the measurement in details (IFCC mod.), identification of possible sources of uncertainty (u) and as well as data from internal quality control and EQAS. Data included: estimation of $\%u_{rw}$ from intralab imprecision (within-run and day to day), calculation of $\%u_{bias}$, combined uncertainty $\%u=(\%u^2_{rw}+ \%u^2_{bias})^{1/2}$ and expanded UM. EQAS was organized by Instand (Germany) and all data for ALT were certificated.

RESULTS

MU evaluation results were similar for both control levels (border and high) used but only higher values are presented: $RSD_{day\ to\ day}=4\%$, $RSD_{within-run}=4\%$, $\%u_{rw}=5.5$, $\%u_{bias}=8.3$ and $\%u=10$.

CONCLUSION

Conclusions: Knowing the MU would make patient results comparable irrespective of where the testing is done as well and our laboratory to improve the quality. We considered high MU of ALT determination in our study. This could be reduced by using higher quality calibrators, checking the measurements by repeating them and better control of the analytical process where many components of uncertainty.