

Revalidation and Harmonization of Existing IFCC Standardized Hepatic, Cardiac, and Thyroid Function Tests by Precision Optimization and External Quality Assurance Programs

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Abstract : Revalidating and harmonizing clinical chemistry analytical principles and optimizing methods through quality control programs and assessments is the preeminent means to attain optimal outcome within the clinical laboratory services. Present study reports revalidation of our existing IFCC regularized analytical methods, particularly hepatic and thyroid function tests, by optimization of precision analyses and processing through external and internal quality assessments and regression determination. Parametric components of hepatic (Bilirubin ALT, γ GT, ALP), cardiac (LDH, AST, Trop I) and thyroid/pituitary (T3, T4, TSH, FT3, FT4) function tests were used to validate analytical techniques on automated chemistry and immunological analyzers namely Hitachi 912, Cobas 6000 e601, Cobas c501, Cobas e411 with UV kinetic, colorimetric dry chemistry principles and Electro-Chemiluminescence immunoassay (ECLi) techniques. Process of validation and revalidation was completed with evaluating and assessing the precision analyzed Preci-control data of various instruments plotting against each other with regression analyses R². Results showed that: Revalidation and optimization of respective parameters that were accredited through CAP, CLSI and NEQAPP assessments depicted 99.0% to 99.8% optimization, in addition to the methodology and instruments used for analyses. Regression R² analysis of BilT was 0.996, whereas that of ALT, ALP, γ GT, LDH, AST, Trop I, T3, T4, TSH, FT3, and FT4 exhibited R² 0.998, 0.997, 0.993, 0.967, 0.970, 0.980, 0.976, 0.996, 0.997, 0.997, and R² 0.990, respectively. This confirmed marked harmonization of analytical methods and instrumentations thus revalidating optimized precision standardization as per IFCC recommended guidelines. It is concluded that practices of revalidating and harmonizing the existing or any new services should be followed by all clinical laboratories, especially those associated with tertiary care hospital. This is will ensure deliverance of standardized, proficiency tested, optimized services for prompt and better patient care that will guarantee maximum patients' confidence.

Keywords : revalidation, standardized, IFCC, CAP, harmonized

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