P-239 - ANALYTICAL VERIFICATION OF THE NEWBORN SCREENING TESTS TO EVALUATE THE PROCESS COMPETENCE.

Mendoza V, Sauza A, Martinez A, Garrido M, Cervantes AK, Portilla EF, Morales I

Ensayos y Tamizajes de México. Ciudad de México - México. asauza@eytmsa.com

INTRODUCTION: The laboratory quality standard implementation is an efficient and useful way to demonstrate and attest competence, through better processes and high quality of results, which provide to the experts of different tools for reliable interpretation. The Ensayos y Tamizajes de México, newborn screening laboratory, accredited in the semi-quantitative neonatal tests: TSH, T4, TGAL and PKU from Tecnosuma; IRT, G6PD, and Biotinidase from Zentech; GALT from Astoria Pacific; as well as the qualitative tests hemoglobins variants from Bio-Rad and Biotinidase from Tecnosuma, under the Mexican standard NMX-EC-15189-IMNC-2015, ISO 15189: 2012. OBJECTIVE: Verify the compliance of the newborn screening tests supported by analytical evidence to confirm their analytical performance when applied under the operating conditions of the laboratory, to confirm their performance against validation specifications of the manufacturer, to determine the tests are suitable for the intended use.

METHOD: For the verification we use “validation and verification of quantitative methods perform by clinical laboratories” as guide, from the standard NMX-EC-INMC-2015. All the tests were processed according with the analytical protocols described in the insert of each test. For semi-quantitative tests linearity, precision intra-assay and inter-assay, veracity and uncertainties were calculated; and for qualitative tests sensitivity, specificity, kappa index, positive predictive value and the negative predictive value were calculated. To calculate those parameters, controls from Centers for Disease Control and Prevention (CDC Atlanta) and calibrators from the commercial kits were used. RESULTS: For IRT the correlation coefficient obtained was 0.99 against of the manufacturer 0.99, the precision intra-assay (% CV) obtained was 9.98 % the manufacturer was 15.07 % and the precision inter-assay (% CV) obtained was 2.35 % the manufacturer was 8.56 %. The verification performance for all test approved the acceptance criteria of the measured and calculated parameters, ratified their performance against validation specifications of the manufacturer and was suitable for the intended use. CONCLUSIONS: Each clinical laboratory has to verify the performance of the reagent to determine the tests are suitable for the intended use. The verification process supports all the results emitted by the Ensayos y Tamizajes laboratory and provide a certainty in the quality of the results.