P-238 - NEONATAL SCREENING REFERENCE MATERIALS. QUALITY ASSURANCE OF KITS PRODUCED IN THE IMMUNOASSAY CENTER

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**INTRODUCTION:** The development of today's society requires increasingly accurate and precise measurements as a fundamental attribute of product and service quality offered on the market. **OBJECTIVE:** To reflect the results in the preparation and evaluation of the Working Reference Materials (WRM) used in the quality control of neonatal kits manufactured in the ImmunoAssay Center (IAC) and utilized in neonatal screening. **MATERIALS AND METHODS:** The Secondary Reference Materials (SRM) were produced from acquired National Institute for Biological Standards and Control (NIBSC) Primary Reference Materials (PRM). Those tests that do not have PRM use commercial stock solutions as raw material for the WRM, prepared by gravimetric methods at three levels concentration: low, medium and high controls in dried blood on filter paper which are verified according to a calibration curve prepared from the secondary standard of each test. The WRM are evaluated with diagnostic batches and a statistical analysis is performed using STATGRAPHICS PLUS 5.0 and Microsoft Excel programs. **RESULTS:** The percentages of relative accuracy of the WRM were between 10% (optimal value) and 20%. Besides, the slope values estimated in the linear regression significance tests were higher than 0.05, the level of significance established for the test; uncertainty limits were established for the WRM between two standard deviations, with a coefficient of variation \( \leq 15 \% \). In UMTEST BIOTINIDASA, visual observation of results was obtained with expected coloration. Tests used in the certification of the UMTEST GAL, PKU and Biotinidase kits, and so in the UMELISAS T4 Neonatal, TSH Neonatal, and 17OH Progesterone ones, are stable and will emit results of greater reliability and traceability for quality control. **CONCLUSIONS:** The use of WRM has allowed the opportune detection of out-of-specification results, constituting a practical, direct and reliable tool in the quality certification of each kit batch, reducing also the costs and time used in the quality assurance of the IAC productions.