P-215 - EVALUATION OF UMELISA® TIR NEONATAL TESTS IN THE AUTOMATIC ANALYZER SUMAUTOLAB

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**INTRODUCTION:** The automatic analyzer from SUMA® technology has been extensively tested under routine conditions. SUMAUTOLAB is intended to fully process all newborn screening tests available until now (TSH, T4, 17 OHP, PKU and GAL). **OBJECTIVE:** To validate and optimize UMELISA® TIR NEONATAL for the determination of immunoreactive trypsin (IRT) levels in dried blood spots on filter paper using SUMAUTOLAB analyzer. **MATERIALS AND METHODS:** Controls were prepared from whole human blood at 55% hematocrit with concentrations between 50 and 160 ng IRT/mL of whole blood and impregnated on Whatman 903 filter paper. Moreover, four controls from the Center for Disease Control and Prevention (CDC), were used to evaluate the performance characteristics. Influence of sample elution, immunoreaction time and interference with other analytes on IRT levels were evaluated. Intra and inter-assay variation coefficients (CVs), were determined from estimating IRT in two replicates of each control, for 30 operating days. CDC controls were measured twofold on 7 consecutive days for evaluating the test recovery. The zero calibrator and 3 samples (31, 15, and 7 ng IRT/mL) were analyzed 40 times to estimate limit of detection (LOD) and limit of quantitation (LOQ). Finally, a comparison between UMELISA TIR semi-automatic test and SUMAUTOLAB was made by linear regression analysis using 1093 newborn dried blood samples. **RESULTS:** Best results were achieved for one and half hours of elution with constant agitation and one hour of immunoreaction. Interference with other analytes was not observed. Intra and inter-assay CVs ranged between 3,5-7% and 5-9,5%, respectively. The average percentage of recovery was over 95%, LOD and LOQ were 2,8 and 4,4 ng/mL blood, a good agreement was obtained when comparing the semi-automatic technology with SUMAUTOLAB (r2> 0,8). **CONCLUSIONS:** UMELISA® TIR NEONATAL can be performed in the SUMAUTOLAB analyzer. The same reagent kit for semi-automatic technology can be used in the SUMAUTOLAB. Furthermore, the instrument offers advantages, such as, the usage of low volumes of reagents, reduction in the processing time and the number of handling errors by operators, and additional control procedures were included which increase the reliability of the system.