P-229 - PRECISION EVALUATION OF THE MULTIPLEX NEOSCREEN4 KIT

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INTRODUCTION: NeoScreen 4 from Intercientifica is a fluorimetric assay on xMAP platform that allows simultaneous quantification, from a single spot of whole blood, of 4 parameters: 17OHP, IRT, TSH and T4. The assay uses high specificity proteins coupled to magnetic microspheres of different colors associated to the biochemical marker to quantify. T4 and 17OHP are analyzed in solution by a competition assay, while IRT and TSH in a like-sandwich assay. In 2018 our laboratory introduced this technology to newborn screening program. Precision was established by CV% calculation.

OBJECTIVE: Evaluate the precision of a multiplex kit for TSH, 17OHP, IRT and T4.

MATERIALS AND METHODS: Two levels of CDC control (low and high for each biomarker) and the three internal controls provided with the commercial kit, were used to establish the precision of the method. Determination of the four biomarkers was carried out during 20 days. All samples were whole blood on filter paper Whatman 903. Calculations were performed using Microsoft Excel.

RESULTS: Coefficients of variation were calculated for each biomarker in both groups of controls. In all cases commercial kit controls showed lower CV% (from 8% to 22%) than CDC Controls CV% (from 11 to 33%). In both types of controls used, T4 and 17-OHP presented lower precision than IRT and TSH. Higher variability is shown in the biomarkers determined by competition assay.

CONCLUSIONS: The different behaviors observed between both types of controls support the need of run a third part quality control to validate each batch. To complete de evaluation of this method it will be necessary to continue with complementary studies and comparison with other methodologies.