P-183 - COMPARISON OF MEASUREMENT PROCEDURES FOR THE NEWBORN SCREENING OF PHENYLKETONURIA AND PERSISTENT HYPERPHENYLALANINEMIAS

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INTRODUCTION: Our program performs the newborn screening (NS) through a two-stage analytical algorithm, with different methods, whose accuracy and linearity were verified for both according to CLSI EP15-A3 and EP6-A. We consider important the results comparison of the 1st stage, new method, with respect to those obtained in the 2nd stage, known method, to define the NS.

OBJECTIVES: Determine if the methods used in the two stages of NS of Phenylketonuria (PKU) and persistent Hyperphenylalaninemas (HPA) are statistically comparable.

MATERIALS AND METHODS: Protocol “Measurement procedure comparison” CLSI EP09-A3. Period September to December 2018. Concentration of Phenylalanine (Phe) in dried blood spots was determined by two methods: evaluated method, enzymatic-colorimetric / BioRad (BR) and comparison method, fluorometric / PerkinElmer (PE). We used 40 samples of patients with PKU and HPA in treatment with medical-nutritional and biochemical follow-up in our program. Samples concentrations were homogeneously distributed in the evaluated range and were processed in duplicate by both methods: For the statistical analysis we used EP Evaluator® 12.0. RESULTS: Concentrations range (mg/dL): 0.7 to 15.7 (PE) and 0.5 to 19.0 (BR). Mean mg/dL ± SD: 7.7 ± 4.2 (PE); 10.5 ± 5.8 (BR). Correlation coefficient = 0.9331. Deming regression analysis, 95% confidence interval: Intercept = -0.514 (-1.43 to 0.115); Slope = 1.442 (1.315 to 1.569); Standard error of the estimates (SEE) = 2.195; Medical decision point (MDP), Phe = 2.0 mg/dL (PE), was obtained 2.4 mg/dL (BR) limits from 1.9 mg/dL to 2.8 mg/dL. CONCLUSIONS: Statistical comparison, BR method respect to PE: There was not evidence of constant systematic error between the measurement procedures: the Intercept confidence interval included zero. There was a significant proportional systematic error; the Slope confidence interval did not include 1. There was no significant difference in the MDP: 2.0 mg/dL was included in the confidence limits. We found an acceptable random error, taking into account the SEE. We conclude, although the proportional systematic error was significant especially for concentrations higher than 3.0 mg/dL, it was considered that the methods are statistically comparable for performing the NS of PKU and HPA, using the cutoff 2.0 mg/dL.