P-182 - COMPARISON OF TWO METHODS FOR MONITORING PHENYLALANINE LEVELS IN PHENYLKETONURIC PATIENTS: COLORIMETRIC VERSUS FLUOROMETRIC.

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BACKGROUND: In order to control Phenylketonuric (PKU) patients, blood phenylalanine (Phe) concentrations are frequently measured. Differences found in Phe levels depending on the method used for the analysis may hinder optimal management of patients. Guidelines suggest maintaining values between 2 to 6 mg/dl to control dietary adherence. We compared Fluorometric method in DBS with MS/MS and HPLC in a previous work and it is currently used by the physicians.

OBJECTIVES: To investigate differences in blood Phe concentrations analyzed by two different commercial methods (Fluorometric vs Colorimetric) used to monitor follow-up patients.

MATERIALS AND METHODS: 226 dried blood samples (Whatman 903) from 35 PKU patients under control were included in this retrospective analysis. All samples were tested by Neonatal Phe kit, PerkinElmer (fluorometric) and Quantase Neonatal Phe Screening kit, BioRad (colorimetric). For statistical analysis MedCalc V13.1.2.0 software was used. To compare methodologies we performed: a) Linear regression between both analytical systems, b) Pearson correlation coefficient and c) Bland Altman (difference % plot). This analysis was repeated after correct the PerkinElmer calibrators concentrations with regard to the ISNS reference preparation (ISNS-RP).

RESULTS: Regression analysis: Phe\textsubscript{BioRad}(mg/dl)=0.03880+1.3920 Phe\textsubscript{PerkinElmer}(mg/dl); 95%CI: a= [-0.2641;0.3417] and b= [1.3482;1.4358] (p<0.0001). Pearson correlation Coefficient 0.9726, 95%CI: [0.9645;0.9789]. Concentration Range Phe\textsubscript{BioRad}: 0 to 35mg/dl. Limits of agreement from Bland Altman plot (difference %): Mean(±1.96DS): -37.4(-117.2;42.4). Statistical analysis PerkinElmer ISNS-RP: Regression analysis: Phe\textsubscript{BioRad}(mg/dl)=0.03880+1.063 Phe\textsubscript{PerkinElmerISNS-RP}(mg/dl); 95%CI: a= [-0.2641;0.3417] and b= [1.0295;1.0964], (p<0.0001). Pearson correlation Coefficient 0.9726, 95%CI: [0.9645;0.9789]. Concentration Range Phe\textsubscript{BioRad}: 0 to 35mg/dl. Limits of agreement from Bland Altman plot (difference %): Mean(±1.96DS): -5.0(-65.9;56.0) Agreement analysis: Phe values obtained by both methods were divided into three groups (mg/dl): A)<2.6; B)2.6-7.8 and C)>7.8. Group A: 83.3%(40/48); Group B: 80.4%(82/102); Group C: 92.1%(70/76). Total agreement: 85.0%

CONCLUSIONS: The discrepancies observed between two commercial methods during the monitoring of patients with PKU are due to differences in the calibration of the assays. Phe levels obtained by the colorimetric method were higher than those obtained by the fluorometric METHOD: When those values were corrected by ISNS-RP (factor=1.3095), they resulted equivalent. Clinical decision limits should be corrected according to the ISNS-RP when used by the neonatal screening method.