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## Comparison parathyroid hormone (PTH) immunoassays on Vitros 3600 and Cobas-e411 analyzers

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### PURPOSE / OBJECTIVES

The main objective of this study was to compare two different immunochemical methods for PTH on VITROS 3600® and Cobas e-411® analyzers. The research was conducted in the Department of Laboratory Diagnostics (DLD) of the University Clinical Hospital Mostar (UCH Mostar) in Bosnia and Herzegovina. The specific objectives of the paper were to investigate the comparability of analytical methods, and to determine the constant and proportional deviations between individual methods.

### MATERIALS & METHODS

Subjects included in the study were patients older than 18 years who were treated in UCH Mostar or were referred to DLD from the Health Centers, with the signed informed consent. The study included 132 respondents (106 women and 26 men). The methods used to analyze PTH concentration were commercially available assays; VITROS Intact PTH, chemiluminescent sandwich method (CLIA), antigen-antibody complex, and Elecsys PTH of the Cobas e-411® analyzer.

### RESULTS

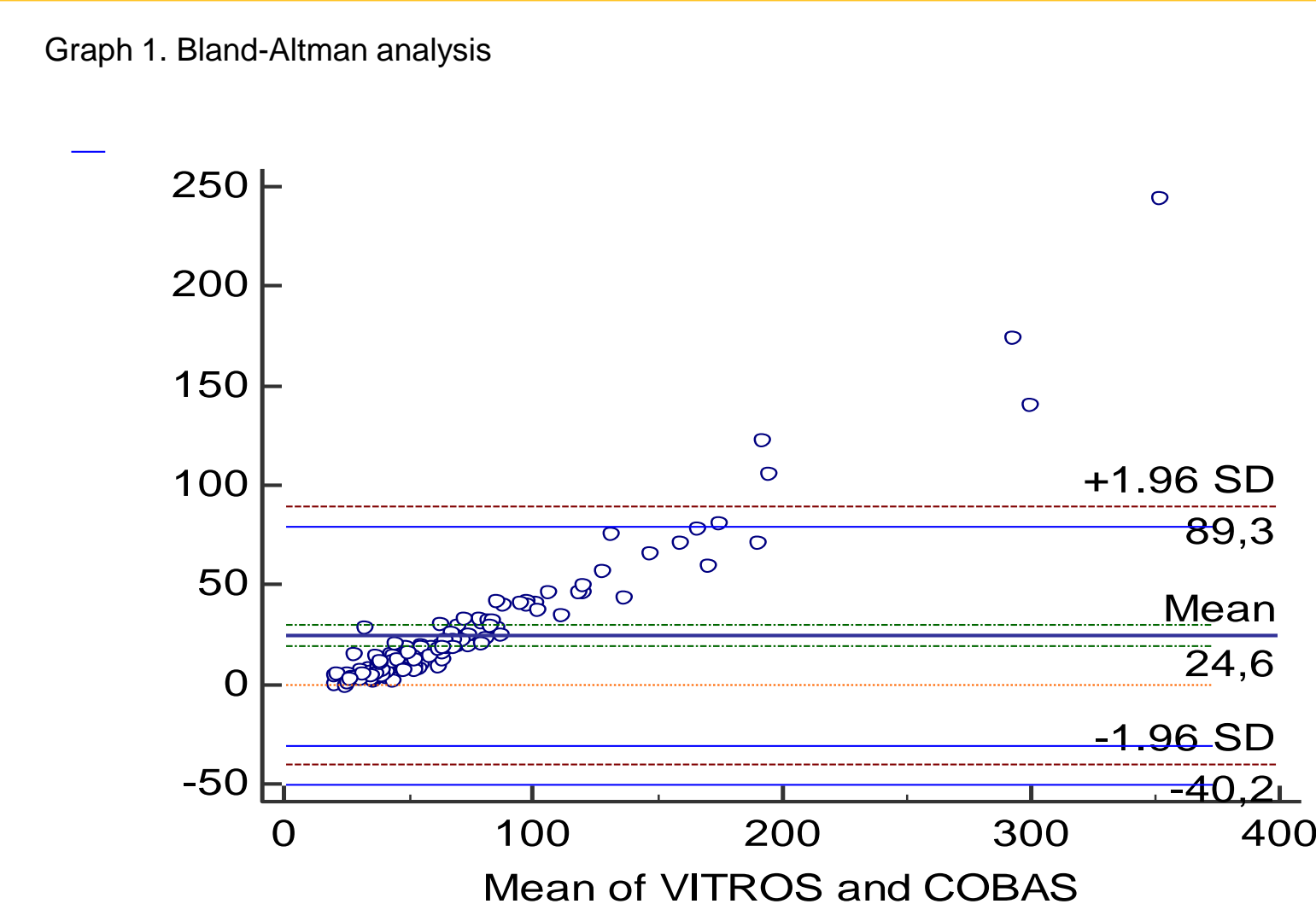


Table 1. Passing Bablok analysis

Variable X	COBAS	Variable Y	VITROS
Sample size	132		
Lowest value	18,5900	26,5000	
Highest value	230,1000	474,1000	
Arithmetic mean	58,2999	82,8852	
Median	48,6200	59,9560	
Standard deviation	37,4483	69,2369	
Standard error of the mean	3,2595	6,0263	
Regression Equation	$y = -16,856185 + 1,676110 x$		
Systematic differences	Intercept A		-16,8562
	95% CI		-19,0484 to -13,7618
Proportional differences	Slope B		1,6761
	95% CI		1,6130 to 1,7260
Random differences	Residual Standard Deviation (RSD)		6,9367
	± 1.96 RSD Interval		-13,5959 to 13,5959
Linear model validity	Cusum test for linearity		No significant deviation from linearity (P=0,21)

The aim of the research was to determine if there was any statistic significant difference in comparison parathyroid hormone (PTH) immunoassays on Vitros 3600 and Cobas-e411 analyzers. The study showed that there was a statistically significant difference in PTH concentrations between these two immunoassays.

### RESULTS

The reference range for PTH; on the Vitros analyzer is 10-65 pg/mL, and on Cobas e-411 is 14,9-56,9 pg/mL. Bland-Altman analysis and Passing Bablok regression in MedCalc software were used for statistical data processing. For Bland-Altman analysis mean difference (MD) between two measurements was 24,5853 (18,8965-30,2741) with limits of agreement  $D \pm 1,96$ .

The results according to Bland-Altman analysis showed statistically significant constant deviation. Passing Bablok regression equation  $-16,856185 (-19,0484 \text{ to } -13,7618) + 1,676110 (1,6130 \text{ to } 1,7260)x$  and showed statistically significant constant and proportional deviation.

### SUMMARY/CONCLUSION

According to the results, it is concluded that the methods are not comparable. Bland-Altman analysis showed that the limits of the confidence interval are different from zero, which confirmed the null hypothesis about the difference and incomparability of the methods. Regression equations, obtained by Passing Bablok analysis, also confirmed that there is a statistically significant difference between these methods and analyzers and that the same method. Also, the differences in measurement by the above methods are greater than the usual analytical variability, and thus may affect the clinical outcome.