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Comparison of two automated assays for the determination of cobalamin in serum

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Introduction

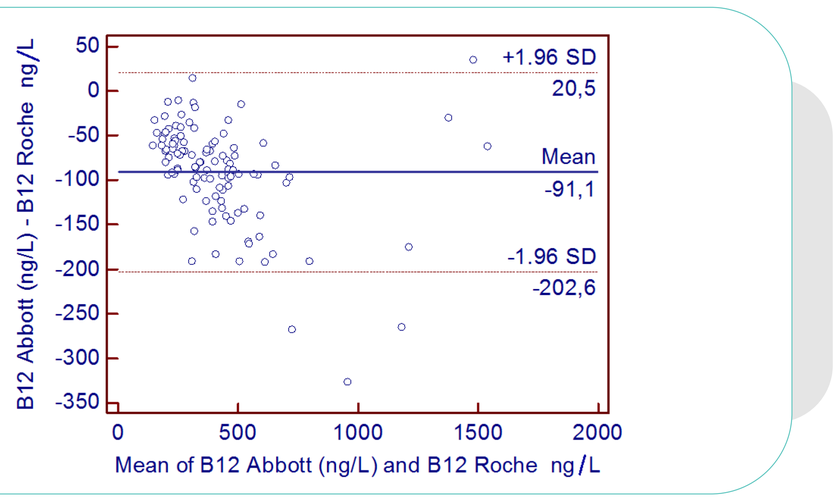
Cobalamin measurement is routinely performed for the screening of vitamin B12 deficiency. Unfortunately, there is no consensus on standardization and no consensus on thresholds used for deficiency. Hence, there is variability between the results of different Vitamin B12 methods leading to potentially different clinical interpretation of the results. In this study, we decided to compare automated assays for cobalamin determination within two different populations, normal and at risk of deficiency.

Material and Methods

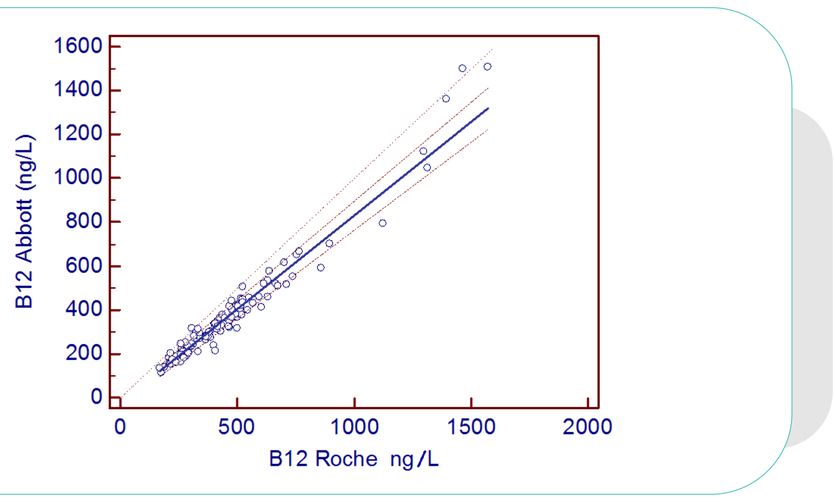
Cobalamin was measured with two different automated immunoassay analyzers: Abbott Architect i1000sr and Roche Modular e602. We compared the two immunoassays in two separate cohorts. The first one consisted of 80 healthy people and the second one consisted of 108 metformin-treated type 2 diabetic patients. Serum cobalamin concentrations were classified as deficient (<200 ng/L), borderline (200-300 ng/L) and sufficient (>300 ng/L).

Statistical analysis:

MedCalc software, version 12.7.7.0 (Oostende, Belgium) was used to perform the Passing-Bablok regressions and Bland-Altman plot.

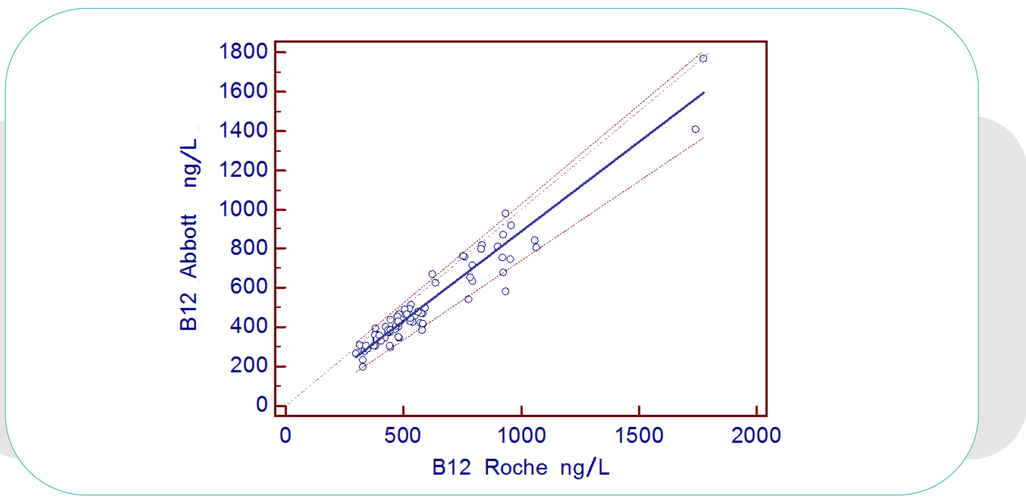


Diabetic population: Bland-Altman plot of Abbott and Roche total Vitamin B12 (ng/L).
Mean difference (solid line) ± 2SD (dashed line) is shown.



Diabetic population: Passing and Bablok was Abbott = -23,7 (95% CI -41; -6.6)+ 0,85 (95% CI 0.80; 0.90)x Roche

Healthy population: Bland-Altman plot of Abbott and Roche total Vitamin B12 (ng/L).
Mean difference (solid line) ± 2SD (dashed line) is shown.



Healthy population : Passing and Bablok regression was Abbott = -25.3 (95% CI -70; 20.7)+ 0.91 (95% CI 0.81; 1)x Roche

Results

In the healthy population, Passing and Bablok regression was Abbott = -25.3 (95% CI -70; 20.7)+ 0.91 (95% CI 0.81; 1)x Roche. Concordance correlation coefficient (CCC), Pearson's correlation (ρ) and Bias correction factor Cb (accuracy) were 0.9105, 0.9611 and 0.9574, respectively.

In the diabetic population, Passing and Bablok was Abbott = -23,7 (95% CI -41; -6.6)+ 0,85 (95% CI 0.80; 0.90)x Roche. CCC, ρ and Cb were 0.9190, 0.9785, 0.9391, respectively. In the diabetic patients' cohort, 15 patients were borderline with Abbott vs. 3 patients with Roche. Three patients were considered as deficient with Abbott whereas the Roche assay did not classify any patient as being deficient.

Conclusions

There was a systematic and a proportional bias between both assays, found similarly in the two cohorts. Results obtained with Abbott were lower than those obtained with Roche and could potentially lead to earlier supplementation. Due to variability of cobalamin results between different manufacturers, cut-off values for deficiency should be verified for each laboratory to avoid misclassification.

References

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Annual Meeting of the Royal Belgian Society of Laboratory Medicine 2019