

CoaguChek® Pro II system: equivalence verification study

Comparison of INR results between the CoaguChek® PT Test on the CoaguChek® Pro II meter and the CoaguChek® XS PT Test on the CoaguChek® XS Plus/Pro meter

Equivalence verification of the CoaguChek® PT Test and the CoaguChek® XS PT Test

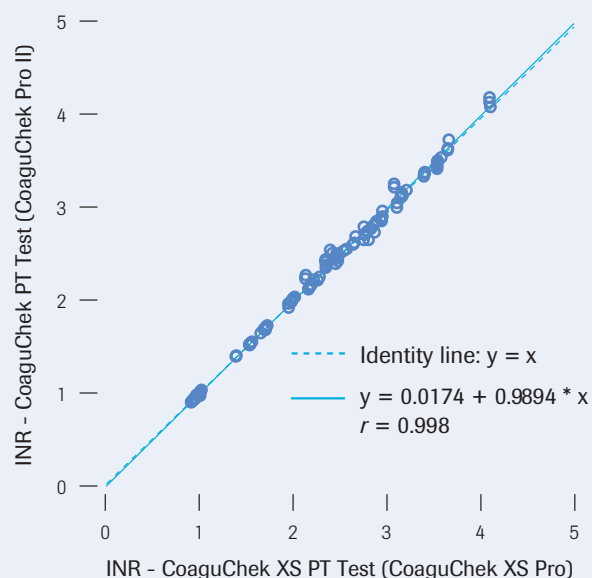
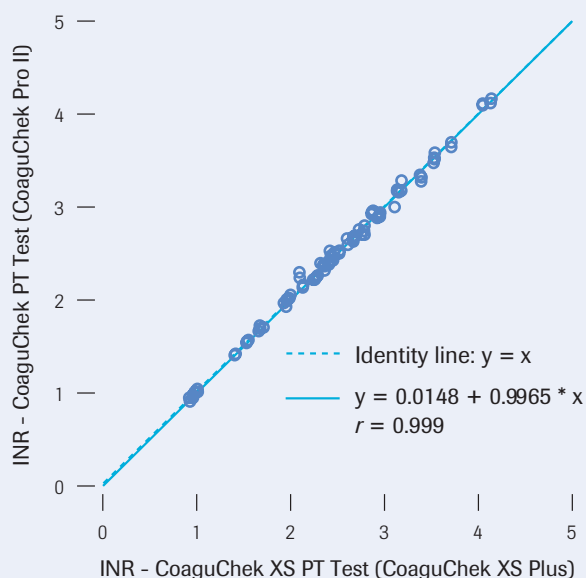
The CoaguChek Pro II system offers multiple enhancements over the CoaguChek XS Plus and CoaguChek XS Pro systems: a broader operating temperature range, an extended menu including an activated partial prothrombin time (aPTT) test as well as a new strip for prothrombin time (PT) measurement, displayed as International Normalized Ratio (INR).

The CoaguChek PT Test¹, to be used on the CoaguChek Pro II system², has a wider intended use compared with its predecessor, the CoaguChek XS PT Test³. In addition to monitoring of patients taking vitamin K antagonists (VKAs), it can now be used to determine PT in patients with suspected deficiencies of coagulation factors of the extrinsic and common pathways, with the exception of fibrinogen.

In an internal equivalence verification study we compared the INR results provided by the CoaguChek XS PT Test used on the CoaguChek XS Plus or CoaguChek XS Pro systems with INR results provided by the CoaguChek PT Test used on the CoaguChek Pro II system. Fresh whole blood samples from 62 donors (40 patients taking VKAs and 22 reference subjects not on VKA therapy) were analyzed in quadruplicate: each donor's sample was measured 4 times, with each measurement carried out on 4 systems simultaneously. INR results provided by the CoaguChek XS PT Test strip and CoaguChek PT Test strip were compared using Passing–Bablok regression analysis.

The CoaguChek PT Test on the CoaguChek Pro II system demonstrated excellent correlation with the CoaguChek XS PT Test on the CoaguChek XS Plus (Pearson's $r = 0.999$) and CoaguChek XS Pro (Pearson's $r = 0.998$) systems.

These data confirm that the proven performance of the CoaguChek XS PT Test^{4,5} is also available with the CoaguChek PT Test on the CoaguChek Pro II system.



Passing–Bablok regression analysis of INR values for the CoaguChek XS PT Test on the CoaguChek XS Plus system and the CoaguChek XS Pro system compared with the CoaguChek PT Test on the CoaguChek Pro II system

The CoaguChek® Pro II system is not available in all markets. Please contact your local Roche representative to obtain the appropriate product information for your country.

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References

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2. Roche Diagnostics (2015) CoaguChek Pro II system operator's manual.
3. Roche Diagnostics (2015) CoaguChek XS PT Test method sheet.
4. Plesch, W., Wolf, T., Breitenbeck, N., Dikkeschei, L.D., Cervero, A., Perez, P.L., et al. (2008). Results of the performance verification of the CoaguChek XS system. *Thromb Res* 123, 381–389.
5. Plesch, W., van den Besselaar, A.M. (2009). Validation of the International Normalized Ratio (INR) in a new point-of-care system designed for home monitoring of oral anticoagulation therapy. *Int J Lab Hematol* 31, 20–25.

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