ACCURACY AND REPRODUCIBILITY COMPARISON OF A PATIENT SELF-TESTING INR MONITORING SYSTEM TO MEASUREMENTS PERFORMED ON AN MLA ELECTRA 900 C® AND BY A WORLD HEALTH ORGANIZATION REFERENCE LABORATORY

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HemoSense INRatio Test Procedure

Turn Meter on. Follow prompts.

Perform fingerstick, Apply sample to Test Strip.

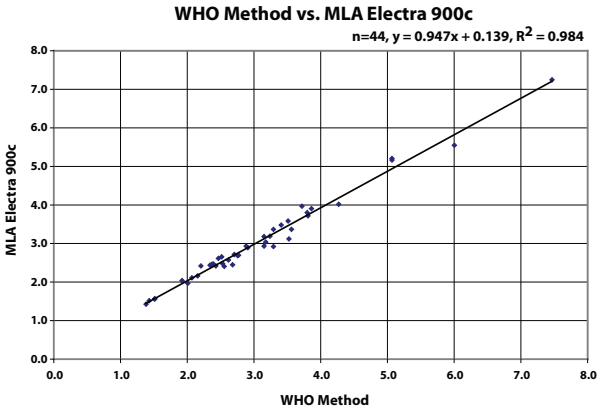
View results in less than 2 minutes.

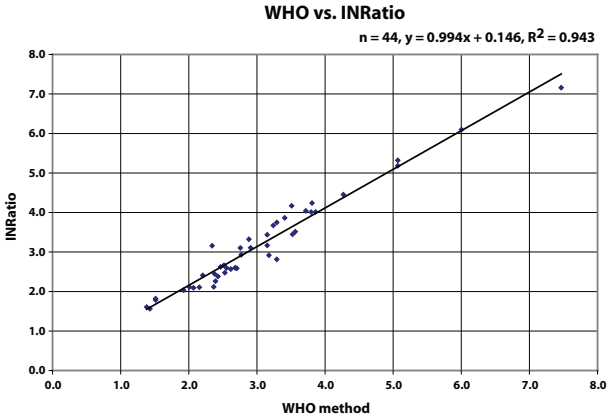
Relevance: As a part of a primary care and laboratory medicine directed approach to oral anticoagulation therapy management, the use of dedicated, compact INR devices are increasingly being utilized in the clinical setting and by patients at home.

Objective: The purpose of this study was to evaluate the accuracy and reproducibility of the HemoSense INRatio® Prothrombin Time Monitoring System, a FDA-cleared patient self-testing INR monitoring system on capillary samples. Capillary samples and simultaneously obtained venous samples were analyzed by a clinical laboratory system (MLA Electra 900C®) as well as in a reference laboratory using a system standardized to the World Health Organization (WHO) reference method for additional verification of the results.

Methodology: Under an institutional review board (IRB) approved protocol, 44 subjects on chronic warfarin therapy were recruited for the study. For each subject, a 15 uL capillary blood sample was obtained from a finger stick and tested in the INRatio device. Within 15 minutes of this testing, a venous blood sample was drawn on each donor. Platelet poor plasma from these venous samples was aliquoted into two tubes and frozen on dry ice. One aliquot was analyzed using an MLA Electra 900C. The second aliquot was sent on dry ice to Leiden University Medical Centre (The Netherlands). INR determination was performed within a month of collection using a method standardized to the WHO INR reference. The three sets of results were compared by regression analysis.

Results: The range of measurements was from 1.3 to 7.5 INR. There was excellent agreement between the Leiden Reference Laboratory and the MLA Electra 900C, as well as with the INRatio. There were no outliers.





Conclusion: The INRatio reliably measured INR accurately over a wide range of values when compared to a widely used clinical laboratory method and a WHO reference lab. This study demonstrates that dedicated, compact INR devices are viable solutions based upon their accuracy and reproducibility for laboratory medical personnel and primary care clinicians involved in the management of patients on chronic warfarin therapy.

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