Prothrombin time (PT) determination in plasma by wet chemistry analysis of blood with concomitant hematocrit determination, Simple Simon PT.

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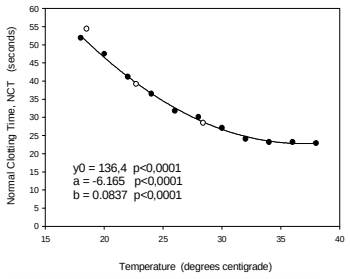
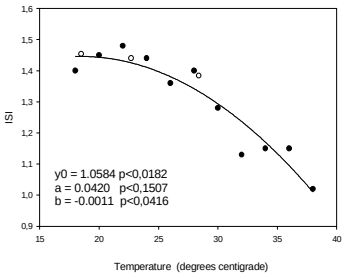
By incorporation of haematocrit (HCT) effects, the study drove at finger-tip blood determinations that agree with reference plasma ditto. The attempt was with wet chemistry and at ambient room temperature, the latter to avoid errors caused by suboptimal temperature control, and to reduce measuring device complexity.

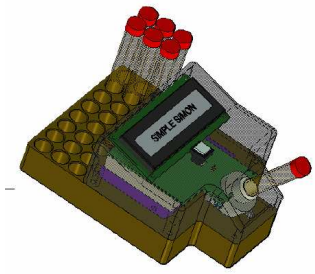
Ambient room temperature PT determination was by measuring the temperature and expressing normal clotting time (NCT) and international sensitivity index (ISI) as temperature functions.

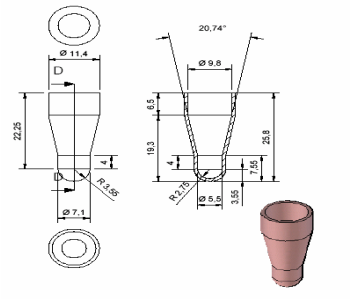
HCT estimate was optical by measuring near infrared light transmitted through reagent only and through the mixture of reagent and blood.

The battery-powered reader had a 5,5 mm optical path-length, 150 µL minimum volume, disposable, polycarbonate reaction container







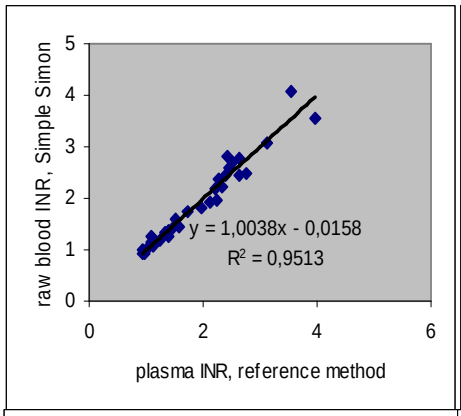


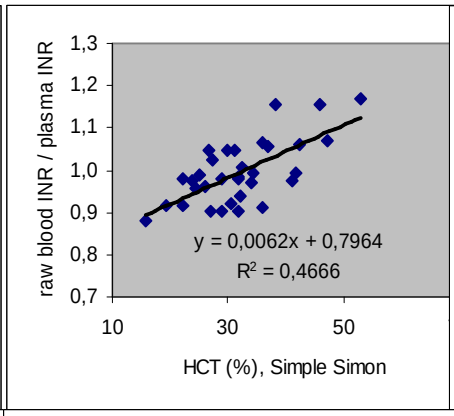
Calibration was with 34 citrated, patient blood samples with known INR values by a reference plasma method. The samples, previously centrifuged to access the plasmas, were repeatedly turned head-over-end to reconstruct citrated bloods.

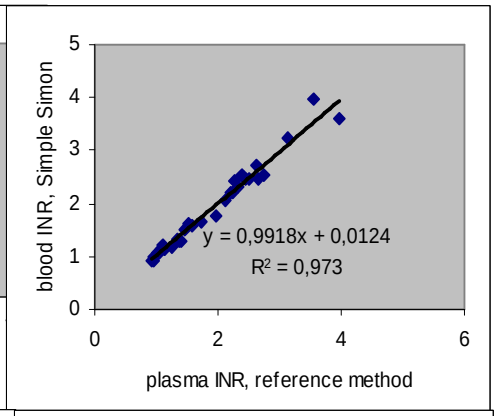
A dedicated Simple Simon PT determination was performed to obtain a ”raw” INR value and the HCT. The raw INR was divided by the known and the ratio plotted against the HCT to obtain a linear regression expression suited for accounting of the HCT effect.

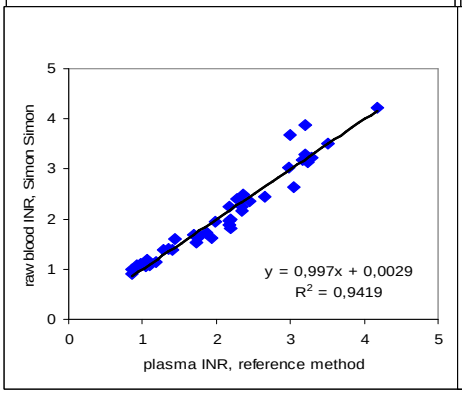
Performance of the method was checked on 59 citrated, patient blood samples with known plasma INR values, analysed as described. The results, prior to accounting for HCT effects, and after, were plotted against the known plasma INR values - the Simple Simon PT results after accounting being the final results. The absence of

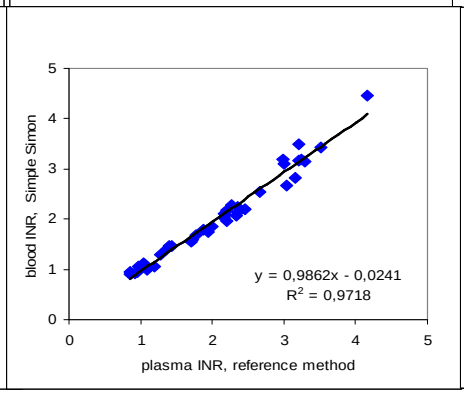
HCT effects in the final results were also demonstrated.

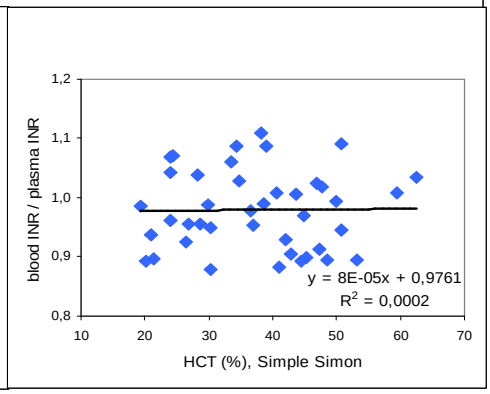












Conclusions

There are HCT effects in determination of PT on blood. The effects amount to about 20% at the extremes. This is naturally unacceptable, but less embarrassing than could be expected from the speculations of Owren and followers, who prophesised that all PT activity resides in the plasma compartment, and none in the cellular.

The above study, on which the Simple Simon PT method is rooted, demonstrates that much of the HCT effects can be accounted for by relatively simple rectifications. The study also demonstrates that ambient room temperature PT determinations on blood can yield results that well agree with those obtained at 37°C with plasma and reference methods.

The study also points at the possibility to reconfigure well functioning wet chemistry procedures to suit point of care demands, and that may

prove to be an attractive alternative to dry chemistry approaches.

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