

The Simple Simon® concept

The product Simple Simon® PT



The Simple Simon®-concept is for near-patient, wet-chemistry, laboratory diagnostic analyte concentration determination, as based on the following philosophy:

- Simple Simon®-products are ‘all-in-one’. Reagents, calibrated reader (measuring unit) and volumetric devices are in the same package (kit) with the same lot number and expiration date. With each lot of product comes a factory-fresh, ready-to-go measuring device.
- Simple Simon® requires neither service nor calibration.
- Simple Simon®-analyses are at ambient room temperature –alleviates the need of temperature equilibration to give quick and precise results.
- Simple Simon® relies on established wet-chemistry methods – minimizes interferences and sample requirements to give highly accurate results.
- Simple Simon®-analysis includes an EVF (hematocrit) estimate and automatically compensates for EVF variations to give results on analysis on blood that harmonize those on plasma by a central hospital laboratory.
- Simple Simon® assays are by the same protocol on samples of capillary blood (finger prick), anticoagulated blood (venous blood) and anticoagulated plasma - the same protocol regardless of sample type.
- Simple Simon® may be quality assured using conventional control plasmas.
- Simple Simon® is suited for a variety of laboratory diagnostic analytes.
- Simple Simon® is battery powered and has a one-button operator interface .
- Intuitive, step by step, procedure. Do as *”Simple Simon says”* on the display.

Simple Simon® PT is intended for determination of prothrombin time, expressed in INR (International Normalized Ration) at POC (point of care) facilities, where capillary blood, anti-coagulated blood and plasma may be analyzed interchangeably.

Simple Simon® PT features:

- PT is according to Owren’s method and results are expressed in INR.
- PT assay performed at ambient room temperature in the range 17 till 45°C.
- PT is performed using the same procedure regardless of samplotype, - capillary blood, anticoagulated blood or plasma, sample volume is 10µL.
- PT-results are automatically corrected for variations in EVF (hematocrit).
- PT assays that can be quality assured using conventional control plasma.

Simple Simon® PT can be connected to networks, printer and scanner through a computer platform and can easily be integrated to existing laboratory data systems and journal systems. The computer platform is developed by Zafena and is based on open source like XML, HL7 and POCT1A, which provides an efficient and economic solution for the user.

Simple Simon® starts by pressing the **Button**.



Simple Simon® guides you through the assay procedure.

ZAFENA develops Simple Simon® according to the IVD guide lines with emphasis on safety, accuracy and ease of operation.

References to Simple Simon PT

1. Lindahl TL et al. INR calibration of Owren-type prothrombin time based on the relationship between PT% and INR utilizing normal plasma samples. *Thromb Haemost.* 2004 Jun; 91(6):1223-31.
2. Ranby M. Coagulation tests at ambient temperature. Patent applicant ZAFENA AB. International Application Number PCT/SE2004/000910, International Publication Number WO 2004/111656.
3. Ranby M. Hematocrit and analyte concentration determination. Patent applicant ZAFENA AB International Application Number PCT/SE2004/001798, in press.

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The figure shows a comparison between PT results obtained by Simple Simon® PT on citrated blood compared to results on corresponding plasmas. The plasma results were from an accredited laboratory of a Swedish University hospital. The comparison comprises 59 samples which consecutively arrived at the hospital laboratory for PT determinations.

Linear regression analysis yielded a regression line with a slope of 1.01 and an intercept of 0.04. The squared regression coefficient was 0.97.

