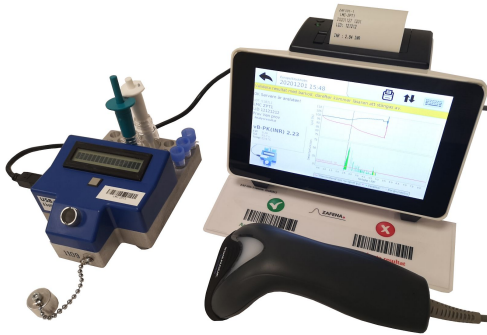


# Simple Simon<sup>®</sup> PT Plus

Measure PT/INR and PT/DOAC



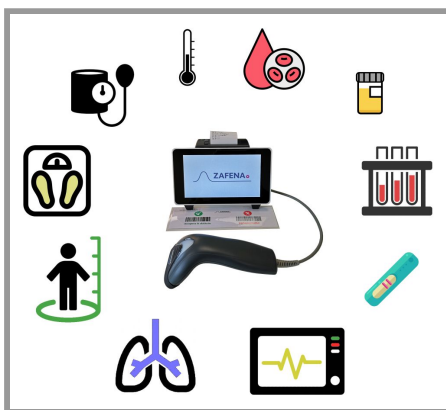
- Wet chemistry according to Owren's method
- Measures Hole blood, venous blood or plasma
- No heating to 37°C. Temperature compensation
- Real time reaction curves, give analytical integrity
- Operational temperature 17°C to 40°C
- Step by step on screen instructions
- Recip printer and +30000 recorded posts
- ASTM, Poct1A, FHIR communication to EHR

## Simple Simon PT Plus

Simple Simon<sup>®</sup> PT Plus is a wet chemical analysis procedure that analyzes PT according to Owren's method. In addition to tissue thromboplastin (membrane-bound tissue factor), the liquid reagent contains coagulation factor V and fibrinogen. The PT determination becomes specific for the vitamin K-dependent coagulation factors II, VII and X and is expressed in an internationally normalized ratio, INR - the PT expression that the WHO advocates. INR is the ratio between measured PT and normal PT. The ratio is harmonized to the equivalent for a WHO reference procedure with an exponent, ISI, international sensitivity index.

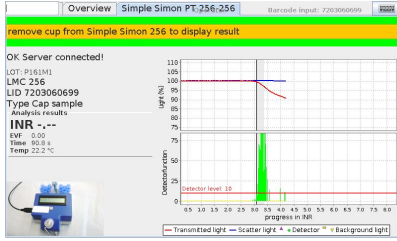
Through innovative methodology, the same analysis procedure, 10 µL sample and 200 µL reagent, can be used for different sample types. Possible test types are native blood (capillary blood), citrate anticoagulated blood (venous blood) or plasma.

The innovations also make it possible to perform the analysis at room temperature between 17 and 40°C (the reader does not need to be thermostated). Simple Simon<sup>®</sup> PT provides close to the same INR values as a hospital laboratory calibrated with reference substance from national calibrators, f.ex. EQUALIS, Sweden.



It is a flexible, modular system, including (a) meter-module, (b) IT-module and (c) barcode scanner. Simple Simon PT Plus can be expanded to handle up to 3 meters for scalability in the laboratory workflow. You can easily widen the product's functionality by adding a meter of different type to the same IT-module (POC-Workstation), f.ex. blood pressure, spirometry or glucose.

Desired / necessary supplementary information, such as the identity of the patient and the identity of the operator, is supplied with the bar code reader, or if desired with the built in touch keyboard.



### Real time reaction curves

Simple Simon PT Plus uses different wavelengths of light to detect the coagulation. These are presented as one blue and one red line on the POC-workstation. When coagel appears, the light is bent and scattered, which is detectable with high precision. The strength of the clot signal is shown through green signal columns at the bottom of the screen. Signal detection threshold is marked by a red line and leaking daylight shows as yellow spikes below the detection line. Real time reaction curves will teach the operator how a “good” curve should look like. This simple function eliminates the need for routinely double tests to be sure of accuracy and reliability. Only if the operator sees a “strange” curve will it be necessary to perform a second test.

### The POC competition

The Simple Simon PT Plus has the features of, and performs like a central wet chemistry lab, but in a point of care environment. This gives the operator the same information and accuracy as a central wet chemistry lab.

Manufacturer	Product	Chemistry method	Sensitive to heparin	Sensitive to Lupus-patients	Analyze time in minutes	Sample size	Real time reaction curves	Analytes	Calibrate against local reference lab	Memory	Connectivity
Zafena	<b>SSPT Plus</b>	Wet Owren	No	No	2	10uL	Yes	PT/INR PT/DOAC	Yes	+30000	ASTM, Poct1A, FHIR, xml
Roche	CoaguChek pro II	Dry Quick	Yes	Yes	5	≥8uL	No	PT/INR aPTT	No	2000	Poct1A
qLabs	MicroPoint	Dry Quick	Yes	Yes	2-7	<10uL	No	PT/INR aPTT	No	200	Poct1A (Only Wifi)
iLine microsystems	micrINR	Dry Quick	Yes	Yes	2-4	≥3uL	No	PT/INR	No	199	Require PC-software
Siemens	Xpreecia stride	Dry Quick	Yes	Yes	2-4	≥6uL	No	PT/INR	No	640	Require PC-software

### References for Simple Simon® PT Plus

- 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.
- Ranby M. Coagulation tests at ambient temperature. Patent applicant ZAFENA AB. International Application Number PCT/SE2004/000910, International Publication Number WO 2004/111656.
- Ranby M. Hematocrit and analyte concentration determination. Patent applicant ZAFENA AB International Application Number PCT/SE2004/001798, in press.

Results with Simple Simon® PT Plus on citrate anticoagulated blood compared to results on corresponding plasma. The plasma analyzes performed by an accredited laboratory at a Swedish University Hospital. The comparison includes 59 samples sent consecutively to the hospital laboratory for medically conditioned PT analysis. Linear regression analysis shows slope and cutoffs of 1.01 and 0.04, respectively a squared regression coefficient of 0.97.

