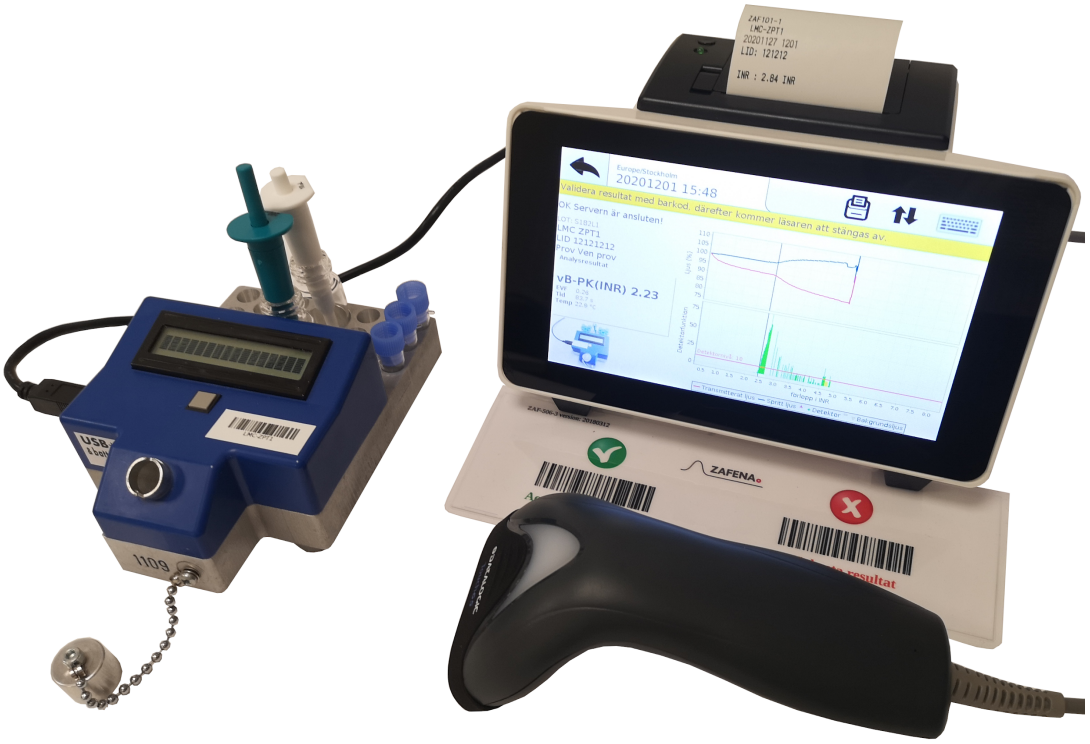
Simple Simon PT Plus

Manual and user guide



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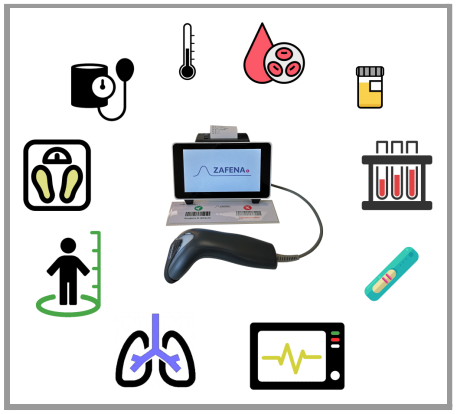
Simple Simon PT Plus

Simple Simon® PT Plus is a Hospital laboratory quality wet chemical analysis procedure that analyzes prothrombin time (PT) expressed in INR. In addition to tissue thromboplastin (membrane-bound tissue factor), the liquid reagent contains coagulation factor V and fibrinogen. The PT determination is 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 sample types are native blood (capillary blood), citrate anticoagulated blood (venous blood) or plasma.

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

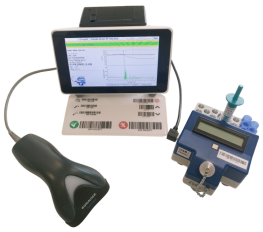


It is a flexible, modular system, including (**a**) meter-module, (**b**) IT-module and (**c**) barcode scanner. Simple Simon PT Plus can be expanded to handle up to 3 meters for scalability in the laboratory workflow. You can easily widen the product's functionality by adding a meter of different type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

Simple Simon PT Plus is a product that is delivered calibrated and contains the following:

- Reader, calibrated with given LOT equipment and consumables
- POC-Workstation for history, receipt printing and connection to EHR.
- A fixed pipette for 10 µL
- A fixed pipette for 200 µL
- Pipette tips
- Reagent tubes and plugs Freeze-dried reagent
- Dissolution buffer
- ZAP, Zafena Abnormal Plasma, which is a lyophilized control plasma with INR values in the therapeutic range of 2-3. The LOT number on the ZAP is independent of the other components in the product.



Readers and reagents belong together LOT-wise. This means that when changing the reagent LOT, the readers and pipettes must be replaced. The readers are marked, both physically and electronically (in terms of software) with a serial number, the current LOT number, and the date of service.
The reader is powered by the USB power from the POC Workstation [ZAF-552].

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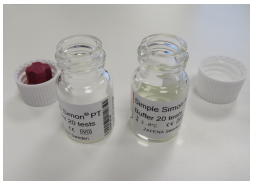
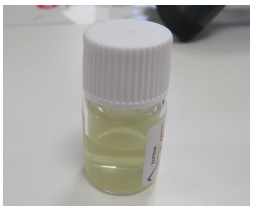
Reagent





• Tissue thromboplastin
• Bovine plasma fractionated with all coagulation factors except those to be measured.

The analysis is of the Owren type. This means that the sample is diluted with reagents in a ratio of 1:21, and that the reagent contains fibrinogen and coagulation factor five (FV) so that the reaction becomes independent of the sample's content of these. The time is taken from the time the sample is added to the reagent until crosslinked fibrin is formed. The clot is detected optically.

The analysis is performed at room temperature and the result is recalculated to what it would have been at 37 ° C. The test is usually performed on whole blood and is then corrected for EVF. This is done automatically in the reader. After reconstitution, the reagent is aliquoted into reaction tubes and then stored in a refrigerator where it is durable for 3 weeks.

Execution

• All components must be room temperature before analysis
• The instrument is started at the touch of a button, followed by instructions given on the meter and on the workstation display.
• 10 µL of sample is added to the reagent.
• It is important that the mixture of samples and reagents is correct. Quality assurance of the system can be done with control plasma. In Simple Simon ® PT the product includes a plasma control, Zafena Abnormal Plasma [ZAF-102-1], with INR values in the therapeutic area.

Sampling

Analysis is performed on capillary blood or venous citrate anticoagulated blood and citrate anticoagulated plasma. Note that when changing the sample type, a barcode scan is required for the correct sample type. This barcode can be found on the enclosed barcode document that comes with it. 10 µL sample is added to the reagent, be sure to wipe off excess sample on the outside of the pipette.

Capillary sample

• Sampling takes place in direct connection with the analysis being performed. If necessary, wash the finger flower with a suitable disinfectant. Let your finger air drought. Stick laterally on the finger flower with lancet so deep that a spontaneous blood flow occurs.
• Collect 10 µL using the white supplied 10 µL pipette [ZAF-101-6-4]
• Remember to hold the pipette at an angle to your finger so that the mouth of the tip is not blocked.

Venous sample

• Take venous blood in tubes with blue cork containing sodium citrate 0.13 mol / L. The pipe must be well filled. Mix by turning the tube 10 times. Before analysis, check that the tube is well filled and that it does not contain clots. The latter can be detected by turning the tube.
• Collect 10 µL using the white supplied 10 µL pipette [ZAF-101-6-4]

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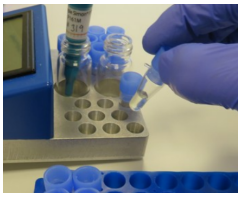
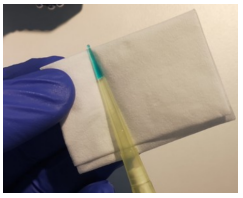
Keep in mind



• For the analysis to be correct, it is important that reagents and readers have the same temperature. Therefore, filled test tubes should be stored in the test tube holder located on the back of the reader for at least 5 minutes before analysis.

• Be sure to wipe the plastic capillary clean of blood / plasma on the outside before analysis.



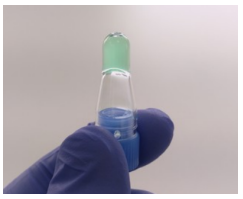
• When pipette tip with sample is inserted into the reaction tube, the analysis starts automatically. At the same time, the sample must be deposited in the reagent. Rinse the pipette tip immediately by pumping with the pipette, so that the sample is mixed with the reagent. During mixing, the pipette tip is kept in the bottom area of the reaction tube to avoid involuntary air mixing. The pumping movement with the pipette should be calm and balanced. Rinse and mix samples and reagents in this way about 7 times until the message "pipette out" appears on the reader's display.

• Proper mixing of samples and reagents is a prerequisite for proper test results. Therefore, use the entire time allowed at the beginning of the measurement to mix samples and reagents.

• When changing the sample type, an extra scan of the bar code for the correct sample type is required to give the correct result. This is because, for example, the venous samples are diluted with sodium citrate, which the reader cannot feel for himself.

• Inspect and check that the sample has coagulated after the analysis has been completed and the reaction tube has been lifted out of the measuring position.

Messages in the meter



These error codes are also displayed in the POC-Workstation view.

Low temperature
Reason: Temperature below the meter limit (+ 17 ° C)
Remedy: The RT must be raised so that the metal block and the meter temperature exceed + 17 ° C

High temperature
Reason: Temperature above the meter limit (+ 40 ° C) Remedy: The RT must be lowered so that the metal block and the temperature of the meter are below + 40 ° C

Weak light
Reason: Blocked or impaired optics
Remedy: Check that the beam path / reaction chamber is free. Clean beam path and reaction chamber. Alt. exchange the meter.

High backlight / Use lid
Reason: Ambient light high. The backlight interferes with the measurement.
Remedy: Use lid during measurement. Do not leave the meter in direct sunlight.

Mix failed
Reason: Insufficient mixture of reagents and samples.
Remedy: Repeat the analysis and mix the sample more vigorously and more permanently.

Replace battery
Cause: The batteries are weak or depleted and need to be replaced. (This only applies to meters that are not connected to the POC-Workstation [ZAF-552])
Remedy: Replace batteries.

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Error (100-400)
Cause: Temporary electronics error.
Remedy: Restart the meter.

INR error
Reason: Clotting criteria not met.
Remedy: Repeat the measurement.

INR error 1
Reason: Too many false clot detector activations.
Remedy: Repeat the measurement.

INR error 2
Cause: Too weak clot detector signal.
Remedy: Repeat the measurement.

INR error 3
Cause: Wrong curve shape on the detector signal. Reaction tube lift out of the reaction chamber prematurely.
Remedy: Repeat the measurement.

INR error 4
Cause: INR <0.7 too low
Remedy: Repeat the measurement.

Messages in POC-Workstation

These error messages appear only in the POC-Workstation display.

Not validated: Validate with barcode or scan LMC-ID for new analysis.
Reason: The analysis is not validated / approved.
Remedy: Approve the analysis by scanning the barcode "ZAF-ACCEPT" or scan the instrument tag on a meter to start a new analysis.

Failed transfer: Scan ZAF-ACCEPT for retry or LMC ID for re-analysis.
Reason: No contact with LIS / journal system.
Solution: Check the POC-Workstation network connection. Check the POC-Workstation server settings.

Not transferred.
Reason: No contact with LIS / EHR
Solution: Check the POC-Workstation network connection. Check the POC-Workstation server settings.

Looking for server ...
Reason: Trying to get in touch with LIS / EHR.
Action: Wait 5 minutes before action. Check the POC-Workstation network connection. Check the POC-Workstation server settings.

Check the network cable.
Reason: No network connection.
Solution: Check the POC-Workstation network connection.

Connect the meter via USB cable and start the instrument.
Reason: No contact with the meter.
Action: Check USB cable between meter and POC-Workstation. Start the meter.

The measurement was interrupted, the analysis was automatically rejected.
Reason: New measurement has been started without it having been previously approved.
Remedy: Repeat the rejected measurement.

Install new batteries in Simple Simon readers.
Reason: Weak or empty batteries.

Remedy: Replace batteries in the meter.

The reader is turned off, the connection was lost.
Reason: No contact with the meter.
Remedy: Check the meter's cable connection and make sure the meter is started.

Please enter operator ID with barcode.
Cause: Operator ID is required, but has not been entered.
Action: Scan operator ID.

Please enter reader number with barcode.
Reason: Meter identity / reader number required.
Action: Scan instrument tag to enter reader number / meter identity.

Please enter the LID number or control number.
Reason: Patient ID / Laboratory ID / Control number required.
Remedy: Scan the patient's identity to the sample in the form of LID / social security number / serial number

Please enter your social security number.
Reason: Social security number to identify the patient's sample is required.
Remedy: Scan the patient's social security number.

Please enter sample type with barcode.
Reason: Select type of sample required for calculation of INR.
Action: Scan the type of sample in question; Whole Blood, Citrate Blood or Plasma.

Sample EVF <8%, Please enter the correct sample type (plasma) before acceptance.
Reason: Measurement was done in plasma, but with sample type set to whole blood or citrate blood.
Remedy: Scan barcode ZAF-PLASMA.

Validate results with barcode.
Reason: The measurement is complete, but needs to be approved by the operator.
Remedy: Approve or reject the measurement via barcode.

Validate the result with barcode, then the reader will be turned off.
Reason: The measurement is complete, but needs to be approved by the operator.
Remedy: Approve or reject the measurement via barcode.

You must scan the operator ID before acceptance.
Reason: The measurement is complete, but lacks operator ID information.
Action: Scan operator ID.

You must scan the LMC ID before acceptance.
Reason: The measurement is complete, but lacks information about the meter's customer-specific ID.
Action: Scan instrument tag / gauge ID.

You must scan the LID number before acceptance.
Reason: The measurement is complete, but lacks information about patient ID / LID.
Remedy: Scan patient ID / LID.

You must scan a social security number.
Reason: The measurement is complete, but lacks information about patient ID / social security number.
Remedy: Scan patient ID / social security number.

You must scan the sample type before acceptance.
Reason: The measurement is complete, but lacks information on sample type.
Action: Scan sample type.

ERROR: the server is not connected.
Cause: No network contact or incorrect server information.

Solution: Check the POC-Workstation network connection and server settings.

ERROR: transfer failed.
Cause: No network contact or incorrect server information.
Solution: Check the POC-Workstation network connection and server settings.

ERROR: analysis response rejected by server..
Reason: The personal number used is not in the medical record system. (Only applies to some EHR systems)
Remedy: Check patient ID.

Failed transfer: Scan ZAF-ACCEPT for retry.
Cause: No network contact or incorrect server information. The reply cannot be forwarded.
Solution: Check the POC-Workstation network connection and server settings.

LID entry too short, try again.
Reason: The number of characters is too few to be interpreted as a LID.
Remedy: Check LID

Social security number entry to short, try again.
Reason: The number of characters is too few to be interpreted as a social security number.
Action: Check social security number.

Check that LOT XXX is used. Scan the LOT barcode on the reagent box
Reason: Verification is required for the correct reagent LOT.
Solution: Scan the LOT number on the reagent box.

INR ERROR: Unable to accept analysis with INR error.
Reason: INR Error cannot be accepted.
Remedy: Repeat the measurement.

INR Manual: Cannot accept an analysis for manual reading.
Reason: INR Manual cannot be accepted.
Remedy: Repeat the measurement.

Contact Zafena: receiving module is missing.
Cause: Technical error.
Action: Contact your supplier.

Cannot approve results before analysis is complete!
Reason: Try to approve the analysis before it is finished.
Remedy: Wait until the measurement is complete.

ERROR: Unable to accept error analysis.
Reason: Measurements with error can not be accepted.
Remedy: Repeat the measurement.

The calculated checksum does not match. Scan the barcodes again.
Cause: The wrong number of calibration barcodes have been entered.
Solution: Scan the calibration codes again.

ERROR: the barcode calibration data does not work with readers.
Cause: Incorrect calibration codes were scanned.
Remedy: Check the calibration document is for the correct LOT to LOT.

WARNING: A calibration parameter differs in the reader.
Cause: A parameter differs and needs to be double-verified.
Remedy: Verify or reject according to instructions.

INR analysis

INR determination is mainly performed to set up and monitor anticoagulation therapy with warfarin preparations such as Marevan and Waran. The assay is also called PT (prothrombin time) or PK (prothrombin complex activity). The treatment prevents the formation of blood clots, thrombosis. Indications for treatment include atrial fibrillation, venous thrombosis and mechanical heart valve. Anticoagulation treatment with warfarin is extensive, about 1.4% of the population in Scandinavia and areas with similar living conditions are treated. The treatment provides good protection against thrombosis, but there is a risk of serious side effects such as bleeding; 0.5-5% per year. Warfarin is a vitamin K antagonist which, when administered, causes the vitamin K-dependent coagulation factors to be formed with reduced biological activity. This prolongs the coagulation time.

When determining INR, the total activity of the vitamin K-dependent factors is measured:
• Factor II (prothrombin)
• Factor VII
• Factor X

INR is defined as the ratio between the coagulation time of the patient plasma and the coagulation time of a normal plasma raised to ISI.

INR stands for International Normalized Ratio
ISI stands for International Sensivity Index
INR = (patient coagulation time / normal coagulation time) ISI

The INR definition relates to an original reference system where the coagulation time was measured by manual rocking of sample-reagent mixture in a 37°C water bath and where the reagent contained reference thromboplastin of human origin designated 67/40. In that analysis system, the ISI value was set to one (1). Harmonization between the analysis systems currently in use and the reference system takes place with the exponent ISI. (Read more about this in the WHO Technical Report series No 889, 1999 http://www.who.int/bloodproducts/publications/WHO_TRS_889_A3.pdf)

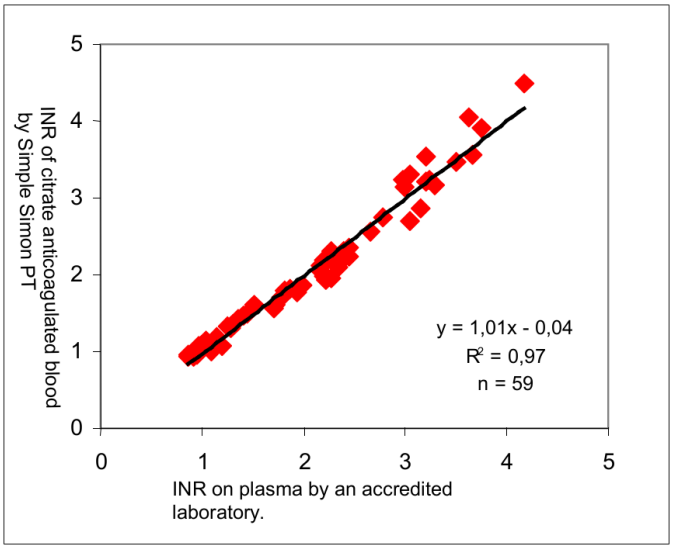
The reference range for the normal range, untreated individuals is INR 0.8-1.2.
The therapeutic range is usually within INR 2.0-3.0, but may also be INR 2.5-3.5.
The risk of bleeding increases at INR values ≥4.5.

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. 5

3. Ranby M. Hematocrit and analyte concentration determination. Patent applicant ZAFENA AB

4. International Application Number PCT/SE2004/001798, in press.



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Practice measurement

Dissolve a bottle of lyophilized reagent with a bottle of buffer. The buffer should be cold. Take reagent and buffer out of the refrigerator and empty the buffer bottle in the bottle with the lyophilized reagent. Mix the contents by inverting the bottle up and down repeatedly for at least 30 seconds. Make sure all content is solved.
Place the appropriate number of reaction tubes (20) in the tube rack. Fill the tubes with 200µL of reagent using the solid green pipette, plug the filled tubes with the blue stopper.

Dissolve one bottle of ZAP control plasma with 400 µL blue ZAP buffer. The ZAP buffer should be cool, this is easily accomplished by holding the cold buffer bottle in your hand for a few minutes before pipetting. Use the solid green pipette. For over correct volume by pipetting the ZAP buffer twice into the vial with it freeze-dried control. Mix the contents by turning the bottle or tipping it from side to side. Do not turn the bottle upside down. Make sure all content is resolved.

Analyze the ZAP control ten times on Simple Simon ® PT.

Test	**INR**
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
average	
Standard dev.	
CV %	

Fill in the table above. The coefficient of variation, CV, expressed as a percentage, shall not exceed 4%. This is most conveniently calculated in Excel spreadsheets by taking standard the deviation divided by the mean multiplied by 100. If the CV exceeds 4%, repeat the exercise again until the CV result falls below 4%.

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Battery replacement

Only applicable to regions running Simple Simon PT stand alone.
Practice a battery change. Remove and replace the batteries in the reader.
Instructions for replacing batteries:

1. Place Simple Simon on a soft surface, to protect the bayonet socket of the measuring position. The reader cover must be in place to protect the measuring position. Turn the reader upside down and loosen the screws that secure the base plate.
2. Remove the base plate and lift the battery box out of the well.
3. Open the battery box by sliding the top of the battery box (one side with a screw hole on one short side and a knurl in the shape of an arrow on the other) in the direction of the screw hole or on the short side where the wires open.
4. Replace the batteries, check that the positive and negative poles are positioned correctly.
5. Close the battery box and put it back in the well.
6. When placing the battery box back in the well, make sure that the wires, one black and one red, are under the battery box and do not get caught when the base plate is screwed on.
7. Screw on the base plate.

Shelf life and storage

Calibrated reader, reagent components, reaction tubes, plugs, pipette tips and pipettes are supplied as one product. The product and its components have the same lot number and expiration date. The expiration date is dictated by the least stable product component, the dry reagent component. Nevertheless, none of the product units is usable after the expiry date has passed and consequently can not, without compromising the manufacturer's responsibility, be used in laboratory diagnostic PT determination. It is assumed that all product components are stored according to the instructions on the individual components of the product components. The dry and wet reagent component as well as the control plasma (ZAP) and its blue-colored solvent should be stored in a cooler, 2 - 8ºC. The other product components, consumables and readers, are stored at room temperature, 17-26ºC.

Cleaning of meters

Wipe with a disinfectant patch, or a cloth / cloth slightly dampened disinfectants and / or isopropyl alcohol. After wiping, the meter can be air-dried or wiped with a dry lint-free cloth. Clean the aisle with a cotton top, lightly moistened with disinfectant and / or or isopropyl alcohol. Use a dry cotton tops to clean in the reaction chamber. Do not use agents that contain bleach or chlorine, as these will wear on the surface. The meter must not be soaked or rinsed in detergent, as liquid can find its way in and affect electronics.

Cleaning the POC Workstation

Wipe with a disinfectant patch, or a cloth / cloth slightly dampened disinfectants and / or isopropyl alcohol. After wiping, the POC-Workstation can be air-dried or wiped with a dry cloth. Do not use agents that contain bleach or chlorine, as these will wear on the surface. The meter must not be soaked or rinsed in detergent, as liquid can find its way in and out affect electronics. Recommendations Surface wiping of the meter should be done once a day. Cleaning the reaction chamber should be performed once a month and / or in case of visible dirt. Surface wiping of the POC-Workstation should be done once a week.

Preparations

1. Dissolution (reconstitution) of lyophilized (lyophilized) reagent. Transfer the contents of a bottle of cold, 2-8 ° C, dissolution buffer to a bottle of lyophilizer reagent. Immediately seal the reagent bottle with the buffer bottle screw cap and gently shake the bottle, alternatively turning it upside down repeatedly, for at least 30 seconds and until all previously dry material is dissolved. Dates are noted on the reagent bottle label. The reagent should be homogeneous and without visible, undissolved particles or lumps, however, it is somewhat opaque. Some of the opacity disappears soon as it consists of small air bubbles coming from the freeze-dried biochemicals. Part of the opacity is permanent as it consists of floating, micrometer-sized thromboplastin particles - membrane fragments from rabbit brain cells that have tissue factor (TF) on their surface. If the dissolution has taken place at too high a temperature,> 15 ° C, the opacity increases and the reagent becomes slightly slower, giving slightly higher INR values. At dissolution temperatures> 25 ° C the effects become noticeable.

2. Portioning and storage of dissolved, ready-to-use reagent. Appropriate handling of dissolved reagent is to dispense into reaction tubes, 200 µL of reagent in each, 15 minutes to 3 hours after dissolution, and seal them with clean blue stoppers. When portioning, the reaction tubes are placed in a rack that is conveniently marked by "peeling" the reagent bottle label with date marking and attaching it to the rack. The reagent should be dispensed with the green, solid pipette provided with the SSPT reader. Automatic pipette, type Eppendorf Repetter, is also possible. Note that with alternative volumetric aids, the need to control the volumes by weighing and to pay extra attention to the INR levels generated when analyzing the ZAP control increases. Within the time interval of 1 to 3 hours after the reagent solution, move the labeled rack with plugged reaction tubes from room temperature to refrigerator temperature (2 - 8ºC). The recommended storage time for refrigerators is a maximum of three weeks. In reagent preparation; Avoid contaminating the reagent, especially with blood or blood plasma. The reagent is by nature very sensitive to coagulation factors, fibrin can be formed and the reagent properties can change. Regularly check INR levels by analyzing the ZAP control. Other control material can be used, but ZAP, product ZAF 102, is especially suitable as the INR level that the SSPT system then generates is directly traceable to established national and international references.

3. Reagent management in connection with analysis. To ensure that the reagent in the reaction tubes has reached the same temperature as the reader, reaction tubes with reagents must be left in the aluminum block of the reader for at least 5 minutes before being used for analysis. Check that the SSPT system generates correct INR levels by analyzing the ZAP control. Dispensed reagent, stored, refrigerated in temperature 2 - 8ºC, needs approximately 1 hour to stabilize at ambient room temperature.

4. Dissolution and handling of the control plasma Zafena Abnormal Plasma (ZAP) is described in detail in sheets that come with the box with the 10 bottles of ZAP. In short, the contents of a bottle of ZAP are dissolved by adding 2x200 µl of cool, 10-15 ° C, blue solution buffer (cold buffer pipetting is not recommended, it becomes light for small volume and somewhat low values). ZAP can be used 10 minutes after dissolution, then stored in the refrigerator and is then usable for two weeks. When ZAP is removed from cold storage, it should be warmed slightly by holding it in your hand for a few minutes. It should be mixed by whipping around in the tube with a pipette tip. Avoid getting ZAP in the cork, residues in the cork evaporate easily and can give a more concentrated liquid and thus lower ZAP values. On the ZAP box there is a bag with closable tubes that is suitable for storing ZAP - small area, less evaporation.

Warnings and precautions

The buffer is harmful to health. The buffer, ZAF 101-2, and consequently the ready-to-use reagent contain sodium azide to prevent bacterial growth and to transfer hemoglobin to a form which allows correct and accurate EVF determination. Azide is a fast-acting poison that, like cyanide, inhibits the body's oxygen transport. Do not drink, or otherwise consume, the buffer or ready-to-use reagent! Rinse with plenty of water if the buffer or ready-to-use reagent is drained. - Do not consume buffer, product ZAF 101-3 or ready-to-use reagent, product ZAF 101-2. The product is harmful if swallowed! - Do not pour the mentioned buffer or ready-to-use reagent into drains that have elements made of lead or copper. Azide combines with said metals to form explosive compounds. Safety data sheets are provided at the request of the supplier and / or of Zafena AB.

The reader and service interval

The simple Simon® PT reader is a device that optically determines coagulation time and EVF. It measures temperature with a thermistor bridge. Using stored calibration values, the reader weighs the measured quantities to an INR value, see above under "**INR analysis**" and ref 4 & 5. In the reader's second state, what comes after the second keystroke, information is given in symbolic form about the battery's condition. Three large heart symbols indicate full battery. As the battery capacity decreases, the heart symbols become smaller and fewer. When only one heart remains, the operator is reminded of the impending battery change by requiring an extra push of a button to proceed. When all the hearts have disappeared, the reader stops analyzing. The battery capacity is used up after about 1200 analyzes, the reader's three batteries, type AA, must then be replaced. When connecting to USB, the power is taken out of the POC-Workstation USB port and the batteries are in theory unlimited. Instructions for battery replacement can be found in the reader's transport box. It can also be downloaded from ZAFENA's website, www.zafena.se. The reader is equipped with an electronic counter. For example, it says "test left: 4006" (the number varies slightly) on the screen so the reader comes freshly serviced from Zafena. With each answer delivered, the number of remaining tests is counted down. When the countdown reaches zero, the reader stops working and must be sent for service. At the moment "autocheck", the reader's second condition, the number of remaining analyzes is also displayed. A low number, reminds that a newly serviced reader should be ordered because the reader stops working at zero.

Components, handling and storage

Simple Simon PT Plus, product ZAF-701, comes in three packages. One with the reader, product ZAF-101-1, one with the POC-Workstation ZAF-552 and the third with consumables, products ZAF-101-2, 101-3 ..... 101-9. The freeze-dried reagent, product ZAF-101-2, comes in the same package as other consumables and must be separated from the rest as soon as possible and stored refrigerated, 2 - 8 ° C. Product components should not be stored or used in direct sunlight Calibrated reader, product number ZAF-101-1. Reagent, 2x 10 bottles with freeze-dried biochemicals, product number ZAF-101-2. Dissolution buffer, 2x10 4 mL bottles, product number ZAF-101-3. White pipette for 10µL, product number ZAF-101-4. Green pipette for 200µL, product number ZAF-101-5. Pipette tip, approx. 425 pieces, which fits both white and green pipette, product number ZAF-101-6. Reagent tube in clear polycarbonate, 400 pieces, product number ZAF-101-7. Reagent tube plugs in blue polyethylene. 400 pieces, product number ZAF-101-8. Instructions for use ZAF-101-9.

Operating temperature

Simple Simon® PT Plus analyzes PT at room temperature within 17 to 40ºC.

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Sample material

The Simple Simon PT Plus Assay is performed on ten (10) microliters of citrate anticoagulated plasma or ten (10) microliters of citrate anticoagulated blood or ten (10) microliters of capillary blood. During capillary sampling, the first drop of blood that comes out is dried.

WARNING! Blood tests and plasma tests can be carriers of infection.
Always wear gloves when sampling and analysis.

Limitations

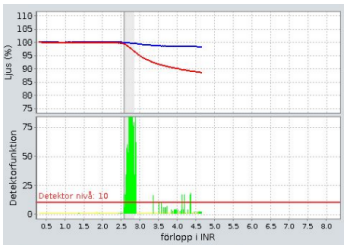
Analysis can not be performed outside the temperature limits 17 to 45 ° C.
Avoid direct sunlight.

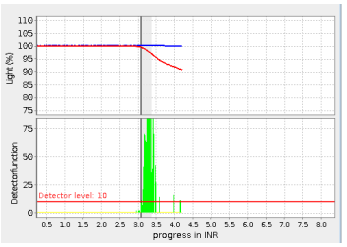
Interpretation of results

PT, prothrombin time, is most conveniently expressed in INR (International Normalized Ratio). INR is the ratio between the clotting times for sample and normal raised to the ISI value of the procedure, see ref 1. PT according to Owren's method is also called prothrombin complex activity, PK and can also be expressed as a percentage of normal. The two expressions are interconvertible, see ref 3.

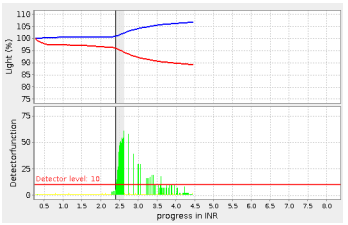
Reaction curve / graph reading

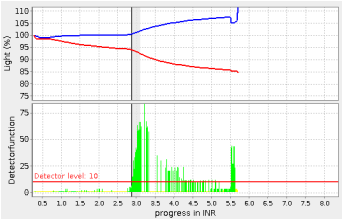
Control material and plasma measurement will generate a flat graph up to the point of clott.
This is due to the opacity of the mixture.
On the right: Two measurements with control solution.



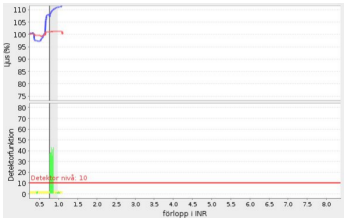


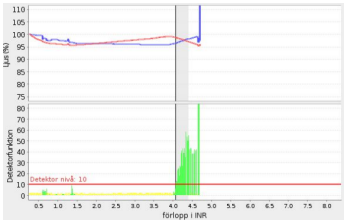
Whole blood and citrate blood will generate a graph in a soft bowe due to the opacity of the mixture.
On the right: Two measurements with whole blood or anticoagulated citrate blood.

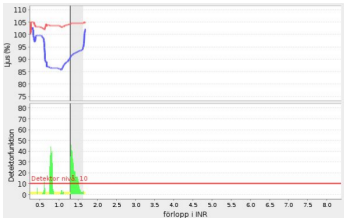


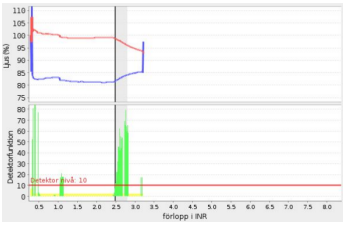


After using the Simple Simon PT Plus for a while, the operator will recognize a correct graph / curve and thus also being able to identify tests that are not performed correct.
Below: Four measurements that we recommend to discard and redo.









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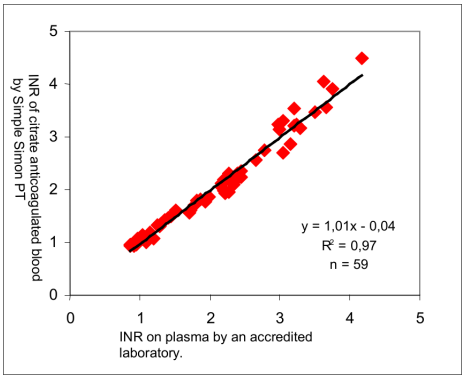
Reference values

Normal range, INR 0.92-1.20 (70-130%). Optimal range for blood-thinning thrombosis prophylaxis, INR 2-3 (15-25%), ref 2.

Measurement performance

Simple Simon® PT measures prothrombin time with the same accuracy as the methods used in hospital laboratories.



Standardization

Simple Simon® PT is delivered calibrated. The product is calibrated directly or indirectly with national calibrators from EQUALIS (ref 3) and international reference method at the coagulation laboratory in Leiden. The calibration procedure follows the recommendations given in the Certificate of Analysis for Calibrators and Control Materials for P-Prothrombin Complex (INR) according to Owren (EQUALIS Version 2.0).

Control material

Control materials for Simple Simon® PT can be freeze-dried control plasmas, comparative plasma or blood controls. Controls can be of the same type as included in the laboratory's regular quality assurance system. The freeze-dried control ZAP included in the SSPT product, Zafena Abnormal Plasma, which has INR values in the therapeutic range, is advantageously used as internal control.

References

1.Besselaar A M H P van den. 1991. The significance of the International Normalized Ratio (INR) for oral anticoagulation therapy. JIFCC 3; 146-53.
2.Schulman S et al 1995. A comparision of six months of oral anticoagulant therapy after a first episode of venous thromboembolism. New Eng J Med 332;1661.
3.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.
4.Ranby M. Coagulation tests at ambient temperature. Patent applicant ZAFENAAB. International Application Number PCT/SE2004/000910, International Publication Number WO 2004/111656.
5.Ranby M. Hematocrit and analyte concentration determination. Patent applicant ZAFENA AB International Application Number PCT/SE2004/001798.

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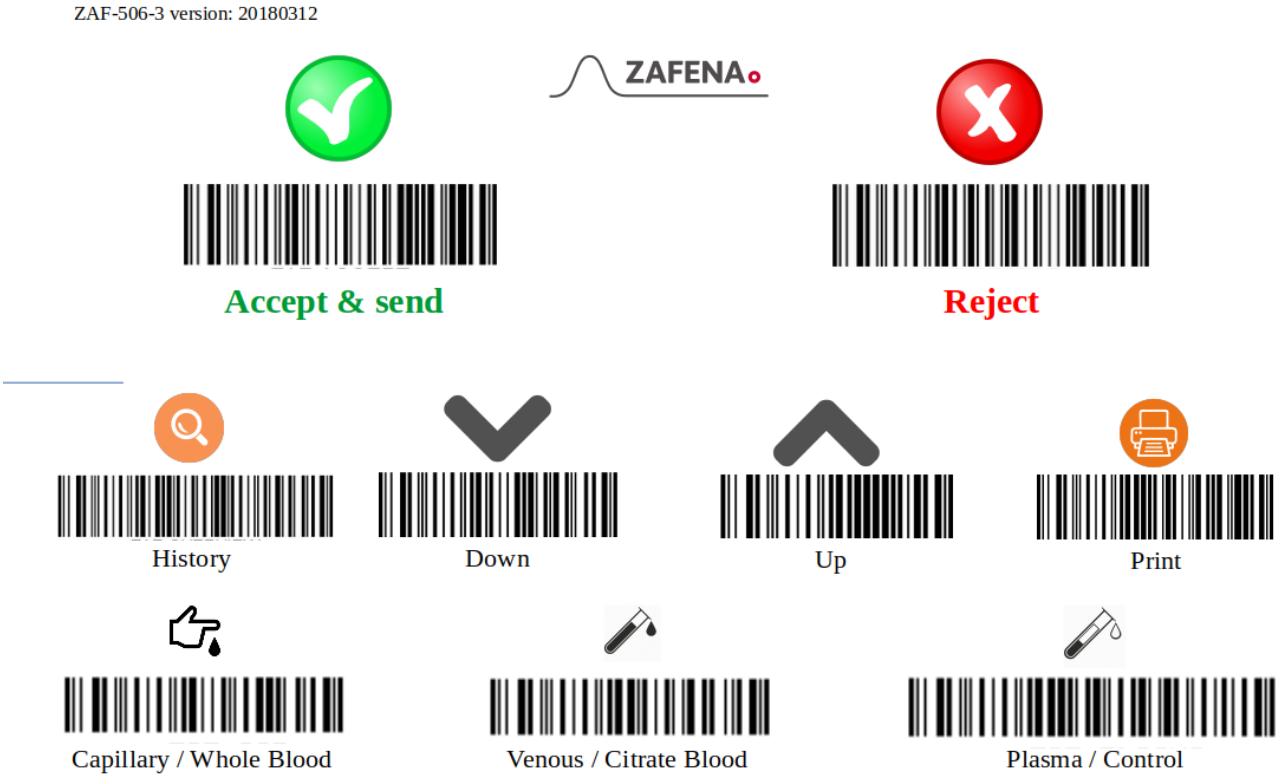
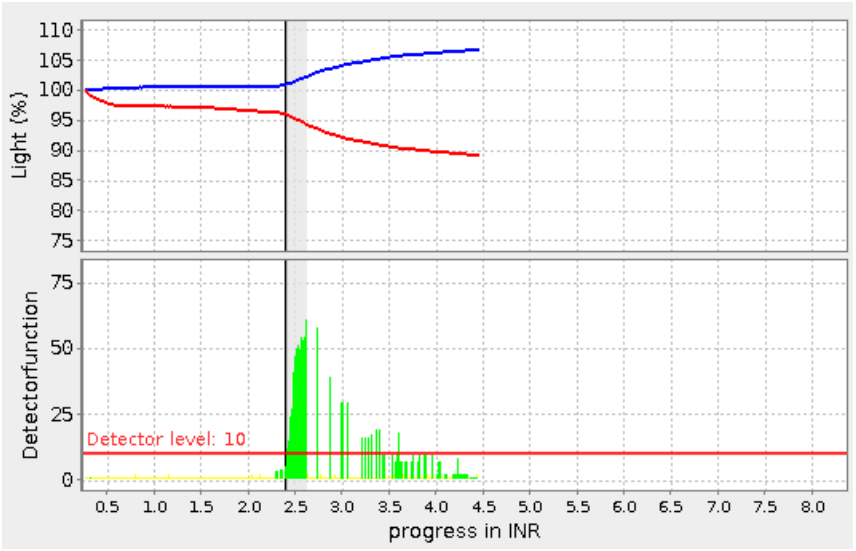
Standard Barcodes

The barcodes needed for everyday use are Accept, Reject, Sample selection, History and Print. These are included with the POC-Workstation, but can also be copied from the picture below.



Reading the reaction graph

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 bendt 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 dubble 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.



Setup

1. Unpack the POC-Workstation [ZAF-552] and connect the power cord from an outlet in the wall to the 12V socket in the unit. Connect the network cable from the POC-Workstation to an activated network outlet in the room. An option is to use the wifi capabilities for communication. Do a visual control that the Micro SD card is inserted into the POC-Workstation memory card slot.

2. Unpack the barcode scanner and connect it to one of the four USB slots in the POC-Workstation.

3. Unpack the meter and connect the included USB cord from the meter to one of the four USB slots in the POC-Workstation.

4. Power the POC-Workstation by pushing the power button on the side of the workstation. Wait until the “Welcome”-view is displayed and the time and date is shown in the POC-Workstation display.

5. Scan the instrument-tag on the meter and follow the instructions on the POC-Workstation display.