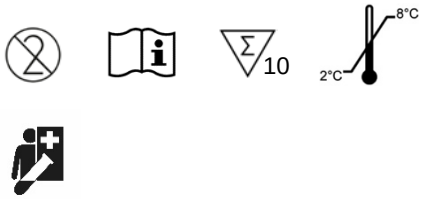
ClotPro

EN

EX-test

REF 113001 CE IVD

For viscoelastic coagulation testing



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For in vitro diagnostic use.

Intended Purpose

EX-test is a ready to use system reagent for the examination of the extrinsic coagulation system in citrated blood for the ClotPro® analyzer [1]. EX-test in combination with the ClotPro analyzer is a semi-automated and semi-quantitative test.

Intended user

For use by trained healthcare professionals. Near patient and laboratory professional use.

Principle

ClotPro is a new generation viscoelastometry system.

In EX-test, $CaCl_2$ re-calcifies the sample and recombinant tissue factor activates the extrinsic coagulation pathway. Polybrene in the reagent antagonizes heparin which may be present in the sample. The coagulation process is continuously monitored by the ClotPro analyzer. The parameters clotting time (CT), clot formation time (CFT), alpha angle (α), amplitudes after CT (e.g., A10, A20, etc.), maximum clot firmness (MCF), maximum lysis (ML), and others are automatically calculated and further described in the ClotPro user manual [3].

The above parameters describe haemostasis from clot activation, clot formation, clot polymerization and clot stability to fibrinolysis [4, 5].

Materials provided

10 sealed single-use pouches containing one active-tip each, providing a dry chemistry reagent composed of recombinant tissue factor, polybrene, $CaCl_2$, buffer and stabilizers. Each pouch contains one desiccant bag.

Additional materials required

- ClotPro analyzer
- Blood collection tube (~0.109 M sodium citrate) for coagulation testing
- ClotPro Cups & Pins
- Pipette

Reagent preparation

The reagent is ready to use.

Storage and stability

Store at +2 to +8 °C. The unopened active-tips are stable up to the expiration date stated on the pouch label.

Unopened pouches may be stored at room temperature for up to 1 month. Opened pouches are for immediate use without delay (testing within one minute after opening).

Warnings and precautions

For use by trained healthcare professionals.

Tips from damaged pouches must not be used!

Human blood samples and control materials are **potentially infectious** and should be handled with care, following general precautions recommended for bio-hazardous materials [7].

General precautions (e.g., wear gloves and minimize skin exposure to specimen and reagents) should be followed when handling all materials. Dispose of waste according to local regulations. A material safety data sheet is available upon request.

Residual Risks

Sources of reagent error:

- Improper use of reagents can lead to wrong test results and cause an incorrect evaluation of the patient's coagulation status.

Sources of procedural error:

- A defective electronic pipette or its improper use can lead to incorrect pipetting volumes and cause an incorrect evaluation of the patient's coagulation status.
- Blood aspired into the Active tip must not be returned into the blood tube as the blood in the tip is contaminated with reagents. In addition, an Active tip which has come into contact with blood must not be used again.
- Poor sample quality due to pre-analytic problems can lead to wrong test results and an incorrect evaluation of the patient's coagulation status.
- Poor sample quality due to improper storage (e.g., the sample is stored for too long before use) can lead to wrong test results and an incorrect evaluation of the patient's coagulation status.
- Wrong sample temperature can lead to impaired test results and an incorrect evaluation of the patient's coagulation status.
- Excessive time elapsed between pipetting steps can lead to wrong test results and an incorrect evaluation of the patient's coagulation status.

Sample collection

Collect the sample according to the recommended procedures [2, 3, 6]. Samples should be analyzed within 3 hours from blood collection. Always ensure blood collection tubes are filled to the indicated fill volume in order to avoid excessive citrate levels.

Test procedure

- Allow the active-tip pouch to reach room temperature and place the blood sample into one of ClotPro´s pre-heating positions. If the sample is cold (< 22°C), it is advised to allow the sample to warm up for 5 min (or more). In evaluations on the effect of pre-warming blood tubes which had room temperature, little to no effect was observed vs. tubes which were not pre-warmed.
- Create the appropriate test in the ClotPro software according to the instructions in the ClotPro user manual.
- Take one Cup&Pin from the box (together) and insert the Pin onto the pin holder by firmly pushing the Cup until a definite stop is reached.
- Remove the Cup and place the pin holder in the parking position.
- Place the Cup into the test position for the respective channel.
- Tear open the active-tip pouch, attach the active-tip to the pipette and aspirate 340 µl sample from the blood tube using the electronic pipette provided with the ClotPro device.
- Dispense the blood sample into the Cup.
- Aspirate and dispense the sample once again to ensure thorough mixing of the reagents with the blood sample. Ensure sample pipetting is performed without interruption of process. Dispose the active tip according to local regulations.
- Take the pin holder from parking position and place it onto the Cup in the test position. The test will start automatically.
- Stop the channel when appropriate and turn the pin holder counter-clockwise (to the left) in order to release the Pin.
- Remove the pin holder and place it into the parking position.
- Remove Cup&Pin (together) and dispose according to local regulations.

Quality control

Plasma-based lyophilized quality control (QC) material is available in 2 levels (QC 1 / QC 2).

The use of control materials for regular QC is recommended. Common practice is to run QC using extrinsically and intrinsically activated viscoelastometry assays (i.e., EX-test and IN-test on the ClotPro analyzer) one level, once per week.

Further information for the use of QC material can be found in the respective product inserts.

Performance characteristics

Precision

Precision was determined with blood of a healthy donor tested on 4 ClotPro analyzers in 6 channels each (n=24).

	Repeatability (inter-channel / inter-device)		
	Mean	SD	CV [%]
CT [s]	59.8	4.5	7.6
A5 [mm]	46.3	1.0	2.2
A10 [mm]	54.3	1.0	1.9
A20 [mm]	58.6	0.8	1.4

Expected values

Expected values have been established analyzing a reference cohort (n=60) of apparently healthy donors.

CT [s]	CFT [s]	A5 [mm]	A10 [mm]	A20 [mm]	MCF [mm]
38 - 65	42 - 93	39 - 58	47 - 64	52 - 67	53 - 68

EX-test is sensitive to systemic fibrinolysis.

Note: Reference ranges may not be identical to setting specific trigger values for therapeutic decision making. Each centre should investigate the transferability of the expected values to its own patient population and, if necessary, determine its own reference ranges.

Limitations and interferences

EX-test contains a heparin inhibitor and is, therefore, largely insensitive to heparin. However, prolongation of the CT may be observed when high doses of heparin are present in the sample. In an in-vitro study, up to 5 IU/ml of unfractionated heparin in the sample did not result in alterations of A5 / A10 / A20.

Abnormal results may be obtained with EX-test under the following conditions:

- Deficiency of coagulation factors in the sample
- Anticoagulant therapy with vitamin K antagonists and direct FX_a / thrombin antagonists
- Fibrinogen deficiency and/or fibrin polymerization disorders
- Thrombocytopenia

Several primary haemostasis disorders e.g., von Willebrand factor deficiency, intake of oral anti-platelet drugs (e.g., acetylsalicylic acid or clopidogrel) are not detected by the EX-test.

EX-test is less sensitive to the effect of oral vitamin K antagonists (warfarin) compared to the prothrombin time.

A fibrinogen deficiency or the presence of substances interfering with clot polymerization may also cause a prolonged CT.

A significantly elevated or lowered haematocrit can influence viscoelastometry measurements [8].

Packaging Symbols

Symbol	Description
	Near patient testing
	Remove Cups & Pins from packaging together
	Do not touch the Pins
	Use Cups & Pins together with Active Tips™

Revision History

Version	Modification
AA	Initial version acc. to regulation (EU) 2017/746 (IVDR)

References

1 Calatzis A., Wittwer M., Leyser H., Hipp Q., Spannagl M. ClotPro – a new generation viscoelastic whole blood coagulation analyser. Hämostaseologie 2018; 4a, A32, P013

2 CLSI/NCCLS H03-A6; Procedures for the collection of diagnostic blood specimens by venipuncture

3 ClotPro user manual

4 Hartert, H. Blutgerinnungsstudien mit der Thrombo-elastographie, einem neuen Untersuchungsverfahren. Klin. Wochenschrift 1948; 26: 577-583

5 Calatzis, A. *et al.* Thromboelastographic coagulation monitoring during cardiovascular surgery with the ROTEG coagulation analyzer, Management of bleeding in cardiovascular surgery edited by Roque Pifarre'; Hanley & Belfus, Inc. Philadelphia, PA, 2000

6 CLSI H21-A5 Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays and molecular hemostasis assays

7 Biosafety in microbiological and biomedical laboratories; U.S. Department of Health and Human Services, Washington, 5th Edition

8 Solomon C. *et al.* Effect of haematocrit on fibrin-based clot firmness in the FIBTEM test. Blood Transfus. 2012 Nov; 20:1-8

Technical Assistance

You can contact us for technical assistance – please see contact details below.

Incident Reporting

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Manufacturer

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