

Instructions for use – FIB RUO assay

For research use only

REF 1060GL – FIB RUO

Intended purpose

The FIB RUO is a research use only assay for viscoelastometry that allows the assessment of coagulation activation, clot formation and clot stability in whole blood following coagulation activation by recombinant tissue factor, recalcification, heparin inhibition by polybrene and platelet inhibition by a combination of cytochalasin D and a glycoprotein IIb/IIIa antagonist.

Principle of the assay



In the FIB test blood coagulation is activated using a combination of recombinant tissue factor, calcium chloride and the heparin inhibitor polybrene, while the effect of platelets on the blood clot is inhibited by the platelet inhibitors cytochalasin D and eptifibatide.

Tissue factor stimulates the extrinsic coagulation cascade via the factors VII, X, V, and prothrombin, which leads to the activation of prothrombin to thrombin. Thrombin converts fibrinogen to fibrin, which leads to the clotting of the sample. This is detected by the clotting time (CT) of the test. The clot formation is characterized by the A5, A10 and A20 parameters, as well as by the maximum clot firmness (MCF).

In the fib assay deficiencies of fibrinogen as well as a disturbed blood clot polymerization can lead to a reduced clot formation, which leads to lower amplitudes in the A5, A10, A20 and MCF.

The use of tissue factor-activated viscoelastometry with platelet blockade was introduced by Calatzis et al [1]. The usefulness of this assay strategy for the assessment of fibrinogen in whole blood was reported by different authors [2][3]. The use of viscoelastometry stimulated by tissue factor with a concurrent platelet blockade in the context of suspected or manifest coagulopathy is a widely used standard procedure [4][5].

Materials provided

10 sealed single-use pouches containing one pipet tip with reagent each, providing a dry chemistry reagent composed of recombinant tissue factor, cytochalasin D, eptifibatide, polybrene, calcium chloride, buffer and stabilizers. Each pouch further contains one desiccant bag.

Additional materials and devices required

- Viscoelastometry analyzer and receptacles (Cups & Pins)
- Electronic pipette for 340 µl with 3 sec aspiration / dispensing cycles
- Blood collection tube (3.2% sodium citrate) for coagulation testing

Reagent preparation

The reagent is ready to use.

Storage and stability

 Store at +2 to +8 °C. The unopened reagent tips are stable until 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 within 1 minute after opening the pouch.

Warnings and precautions

For professional use by trained personnel.



Do not use tips from defective pouches or from pouches missing the desiccant pack.



Intended for single use - do not reuse.

Human blood samples should be handled with care, following general precautions recommended for bio- hazardous materials [6].

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.

Sample collection

Collect the sample according to the recommended procedures [7][8]. Samples should be analyzed within 3 hours from blood collection. Always ensure blood collection tubes are filled to the indicated fill volume to avoid excessive citrate levels.

Test procedure

1. Check the expiry date of the device. Expiry date format is yyyy-mm-dd. Do not use expired product.
2. Allow the reagent tip pouch to reach room temperature.
3. If the sample is cold (< 22°C) it is advised to allow the sample to warm up for 5 min on the heated position of the viscoelastometry analyzer. 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.
4. Create the test in the software of the viscoelastometry analyzer according to the analyzer manual.
5. Place the Cup and Pin into the analyzer according to the analyzer manual.
6. Tear open the reagent tip pouch, attach the reagent tip to the electronic pipette and aspirate 340 µl sample from the blood tube.

7. Dispense the blood sample into the Cup.
8. Aspirate and dispense the sample once again to facilitate thorough mixing of the reagents with the blood sample. Ensure sample pipetting is performed without interruption of the process.
9. Start the test as described in the analyzer manual.
10. The test will stop, or you can stop the test as described in the analyzer manual.
11. Remove the Cup & Pin and dispose according to local regulations.

Quality control

Plasma-based quality control materials can be used to confirm the stability of test results determined with the FIB assay over time.

Result interpretation and expected values

The interpretation of the fib assay is performed using the A5, A10, A20 parameters for the evaluation of the clot formation. The CT and ML parameters can be regarded as process monitors, which show whether a proper coagulation activation and clot stability is found during the analysis.

The clot curve determined during the analysis should be smooth and not noisy. Repeat measurements with irregular curves.

Substances that interfere with the fibrin clot polymerization, may decrease the clot firmness in the FIB assay. Thrombocytosis may increase the clot firmness in the FIB test, because of an incomplete blockade of platelet contribution to clot firmness in FIB. Therefore, the FIB assay as a functional assay of clot formation is not a pure representation of the fibrinogen concentration as determined by the Clauss fibrinogen or other plasma-based fibrinogen assays.

Manufacturer



APIRO Diagnostics Kft.

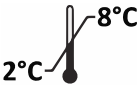
Liget utca 3/2, HU-2040 Budaörs, Hungary

+36 30 203 3334 / info@apiro.eu / <http://www.apiro.eu>

Symbols

Symbol	Meaning
	Manufacturer
	Batch code

Symbol	Meaning
	Use-by date
	Catalogue number

Symbol	Meaning
	Country of manufacture
	Temperature limit
	Consult instructions for use or electronic instructions for use
	Contains human blood or plasma derivatives

Symbol	Meaning
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Contains sufficient for <n> tests

References

- [1] Calatzis An, Fritzsche P, Kling M, Calatzis Al, Mielke L. A new technique for fast and specific coagulation monitoring. European Surgical Research. 1996; 28
- [2] de Vries JJ, Veen CSB, Snoek CJM, Kruip MJHA, de Maat MPM. FIBTEM clot firmness parameters correlate well with the fibrinogen concentration measured by the Clauss assay in patients and healthy subjects. Scand J Clin Lab Invest. 2020 Nov;80(7):600-605
- [3] Yoshii R, Sawa T, Kawajiri H, Amaya F, Tanaka KA, Ogawa S. A comparison of the ClotPro system with rotational thromboelastometry in cardiac surgery: a prospective observational study. Sci Rep. 2022 Oct 14;12(1):17269. Scala E, Marcucci C. Massive Hemorrhage: The Role of Whole Blood Viscoelastic Assays. Hamostaseologie. 2020 Nov;40(4):515-523
- [4] Scala E, Marcucci C. Massive Hemorrhage: The Role of Whole Blood Viscoelastic Assays. Hamostaseologie. 2020 Nov;40(4):515-523
- [5] Heubner L, Mirus M, Vicent O, Güldner A, Tiebel O, Beyer-Westendorf J, Fries D, Spieth PM. Point of care coagulation management in anesthesiology and critical care. Minerva Anesthesiol. 2022 Jul-Aug;88(7-8):615-628
- [6] Biosafety in microbiological and biomedical laboratories; U.S. Department of Health and Human Services, Washington, 5th Edition
- [7] CLSI/NCCLS H03-A6; Procedures for the collection of diagnostic blood specimens by venipuncture
- [8] CLSI H21-A5 Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays and molecular hemostasis assays

Version history of these instructions for use

Date	Version	Change description
2025-03-26	1	Initial version